Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of Cognitive-Behavioral Therapy-Based Intervention on Cognitive Flexibility, Intolerance of Uncertainty, and Rumination in Female Students with Future Anxiety at Islamic Azad University

Protocol summary

Study aim

The Effectiveness of a Cognitive-Behavioral Therapy-Based Intervention on Cognitive Flexibility, Intolerance of Uncertainty, and Rumination in Female University Students with Future-Related Anxiety at the Islamic Azad University

Design

A randomized, parallel-group, open-label, controlled clinical trial involving 40 patients. The `rand` function in Microsoft Excel will be used for randomization.

Settings and conduct

The statistical population for the present study consists of female students experiencing future-related anxiety at the Ahvaz Branch of the Islamic Azad University who visit the university's "Amin" Counseling Center during the designated study period. A convenience sampling method will be employed to select the sample. Following the selection of 40 participants—based on the study's inclusion and exclusion criteria—they will be randomly assigned to either an "intervention group" (receiving a cognitive-behavioral therapy-based intervention) or a "control group" (placed on a waiting list).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female students aged 18 to 30 years who score above the standard cutoff point on the Future Anxiety Questionnaire, indicating a high level of future anxiety. Exclusion criteria: Presence of acute psychiatric disorders, psychotic disorders, or active suicidal ideation (based on clinical interview or self-report); current history of substance or alcohol abuse.

Intervention groups

Intervention group: All female students experiencing anxiety about the future who will receive an intervention based on cognitive-behavioral therapy. Control group: All female students experiencing anxiety about the future who will not receive any intervention.

Main outcome variables

Cognitive flexibility, Tolerance of Uncertainty, Rumination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261020071507N1**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **prospective**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

Registration date

2026-11-07, 1405/08/16

Registrant information

Name

Elahe Bayramzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 8421

Email address

elahe.bairamzadeh@iau.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-11, 1405/08/20

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Cognitive-Behavioral Therapy-Based Intervention on Cognitive Flexibility, Intolerance of Uncertainty, and Rumination in Female Students with Future Anxiety at Islamic Azad University

Public title

Investigating the Effect of a Cognitive-Behavioral Intervention on Cognitive Components in Female University Students with Future Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being enrolled at the Islamic Azad University Being a female student aged 18 to 30 Scoring above the standard cut-off point on the Future Anxiety Questionnaire, indicating a high level of future anxiety

Exclusion criteria:

Presence of acute psychiatric or psychotic disorders, based on clinical interview or self-report Concurrent participation in other psychotherapy sessions or workshops related to the research variables within the 3 months prior to the start of the study Current history of substance or alcohol abuse

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The study population consists of female students at the Islamic Azad University who experience anxiety about the future and visit the university’s counseling center during the designated study period. A convenience sampling method will be employed to select the sample. Once a sample of 40 participants is selected based on the study’s inclusion and exclusion criteria, they will be randomly assigned to either an "intervention group" (receiving a cognitive-behavioral therapy-based intervention) or a "control group" (placed on a waiting list). Randomization will be conducted using a permuted-block design with varying block sizes (4 and 6) by an independent statistician who is not involved in the study's implementation. The randomization sequence will be generated using the RAND function in Microsoft Excel and placed into opaque, sealed, and numbered envelopes to ensure that neither the researcher nor the participants are aware of the allocation sequence (allocation concealment). The envelopes will be opened—revealing the assigned group—only at the time each participant enters the study. To ensure the comparability of baseline variables (such as anxiety levels and age) between the two groups, their distribution will be examined during the statistical analysis phase.

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, Ahvaz

Street address

Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

6134937333

Approval date

2026-10-13, 1405/07/21

Ethics committee reference number

IR.IAU.AHVAZ.REC.1405.572

Health conditions studied

1

Description of health condition studied

Anxiety disorders related to the future

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Cognitive Flexibility

Timepoint

1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement

The Cognitive Flexibility Questionnaire by Dennis and

Vander Wal (2010) will be used to assess cognitive flexibility.

2

Description
Tolerance of Uncertainty
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
To assess intolerance of uncertainty, the Intolerance of Uncertainty Scale by Freeston et al. (1994) will be used.

3

Description
Rumination
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
To assess rumination, the Ruminative Responses Scale by Nolen-Hoeksema and Morrow (1991) will be used.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Duration of each session: 90 minutes. Total number of sessions: 8. Frequency: Twice weekly. Therapeutic tools: This intervention is based on a standard Cognitive-Behavioral Therapy (CBT) protocol. Key components include: guided talk therapy; cognitive assessment and restructuring of catastrophic thoughts regarding the future; mindfulness and muscle relaxation techniques; methods to enhance cognitive flexibility; exposure to uncertainty; and strategies to interrupt negative automatic thoughts and rumination. Intervention content: Session 1: Pre-testing, participant introductions, explanation of the CBT rationale, exploration of the nature of future-oriented anxiety, and identification of maladaptive thought patterns. Session 2: Training on how to identify and record negative automatic thoughts and cognitive distortions related to future uncertainties, and examining the interplay between thoughts, emotions, and behaviors. Session 3: Instruction and application of cognitive restructuring techniques to challenge irrational beliefs and foster cognitive flexibility. Session 4: Utilization of mindfulness techniques and a focus on the present moment to reduce rumination and future-oriented worries. Session 5: Practicing exposure to uncertainty, developing problem-solving skills, and mentally engaging with ambiguous future scenarios to increase tolerance for uncertainty. Session 6: Examining cognitive and behavioral barriers to change, and analyzing the factors that maintain rumination and anxiety about the future. Session 7: Instruction in relaxation techniques, along with a review and consolidation of the cognitive-behavioral skills learned for managing daily stressors. Session 8: Summarizing the sessions, reviewing group achievements, assigning relapse-prevention tasks, administering the post-test, and establishing a specific schedule for the follow-up assessment.
Category
Treatment - Other

2

Description
Control group: The control group will not receive any intervention during the conduct of the study; however, to prevent threats to the study's internal validity—such as compensatory rivalry or demoralization—they will receive the intervention after the data collection phase.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Counseling Center, Islamic Azad University of Ahvaz
Full name of responsible person
Elaheh Bayramzadeh
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Phone
+98 902 699 3731
Email
elahe.bairamzadeh@iau.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Egdarnezhad
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province

Khouzestan

Postal code
6134937333

Phone
+98 61 3334 8421

Email
a_eigder@ymail.com

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
Elaheh Bayramzadeh

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Phone
+98 61 3334 8421

Email
elahe.bairamzadeh@iau.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elaheh Bayramzadeh

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Postal code
6134937333

Phone
+98 61 3334 8421

Email
elahe.bairamzadeh@iau.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Elaheh Bayramzadeh

Position
Master's Student

Latest degree
Bachelor

Other areas of specialty/work
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Email
elahe.bairamzadeh@iau.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable