Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of transdiagnostic psychotherapy and compassion-based psychotherapy on anxiety sensitivity, ambivalence, metacognitive beliefs and emotions in patients with generalized anxiety disorder

Protocol summary

Study aim
Determining the difference in effectiveness of transdiagnostic psychotherapy and compassion-focused psychotherapy on anxiety sensitivity, metacognitive beliefs, metaemotions and ambivalence in patients with generalized anxiety disorder

Design
A clinical trial with two interventions and one control group with one-sided blind parallel groups on 45 subjects. JPower software was used for the randomizer

Settings and conduct
A semi-experimental design of three groups will be used for the implementation of therapeutic interventions and for competitive validation, the first group of meta-diagnostic psychotherapy, the second group of psychotherapy based on self-compassion, and the third control group, along with pre-test and post-test and continuous follow-up. The statistical population consisted of people suffering from generalized anxiety disorder who referred to the psychological service centers of Mashhad, who will enter the research process after the diagnostic interview and confirmation of the main diagnosis of generalized anxiety disorder by a clinical psychologist or psychiatrist. The people present in the groups were informed about the intervention method does not have (one-way blinding)

Participants/Inclusion and exclusion criteria
1-Diagnosis of generalized anxiety disorder 2-Having minimum cycle education and sufficient motivation to participate in the meetings 3- Age range between 18 and 50 years

Intervention groups
Three groups will be used for the implementation of therapeutic interventions, the 1st group of meta-diagnostic psychotherapy, the 2nd group of psychotherapy based on self-compassion, and the third control group, along with pre-test and post-test and continuous follow-up were used.

Main outcome variables
Anxiety sensitivity, metacognitive beliefs, metaemotions and ambivalence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230416057921N1**
Registration date: **2025-07-11, 1404/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-11, 1404/04/20**
Update count: **0**

Registration date
2025-07-11, 1404/04/20

Registrant information

Name
Faezeh Bahri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30

Expected recruitment end date
2025-09-21, 1404/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of transdiagnostic psychotherapy and compassion-based psychotherapy on anxiety sensitivity, ambivalence, metacognitive beliefs and emotions in patients with generalized anxiety disorder

Public title
Comparing the effectiveness of transdiagnostic psychotherapy and compassion-based psychotherapy on anxiety sensitivity, ambivalence, metacognitive beliefs and emotions in patients with generalized anxiety disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of generalized anxiety disorder
Exclusion criteria:
Substance abuse
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
"In this study, a simple randomization method was used to randomly assign participants to the intervention and control groups. Initially, a list of all eligible participants was created, and each was assigned a unique identification code. Subsequently, participants were assigned to groups completely at random using random number generation software. All randomization steps were designed to prevent bias. The allocation process was performed by an independent individual who was unaware of the purpose and hypotheses of the study. This individual recorded the random sequence on a sheet with codes and assigned groups, and this information was not disclosed to any of the researchers currently enrolling participants. This ensured that group selection was conducted fairly and without any external influence. Additionally, allocation information is kept in an encrypted file accessible only to the independent individual. These documented and transparent processes provide the necessary conditions for realizing random allocation and will increase the validity of the study results."
Blinding (investigator's opinion)
Single blinded
Blinding description
“In this study, participants will be provided with general information about the aims and methods of the study. However, the precise details of the intervention in the other group will not be disclosed to the participants in order to prevent potential bias. Therapy sessions for both groups (intervention and comparison) will be conducted similarly in terms of structure, number of sessions, and setting to minimize the perceived differences between the interventions for the participants. The outcome assessors, who administer the questionnaires during the pre-test and post-test phases, will also be blinded to group allocation. The data analyst will also operate in a blinded manner, and the data will be analyzed without group identifiers.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Azad University, Sari branch
Street address
13th Floor, Block A, Ministry of Health and Medical Education, Iran Broadcasting Rd, Between Falmak-e Jonoubi and Zarafshan, Shahrak-e Qods (Gharb), Tehran, Iran
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Province
Mazandaran
Postal code
323232323
Approval date
2023-02-15, 1401/11/26
Ethics committee reference number
IR.IAU.SARI.REC.1401.245

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

The primary outcome is anxiety sensitivity, measured by the original 16-item Anxiety Sensitivity Index (ASI) developed by Reiss et al., 1986. This outcome will be assessed at two time points: pre-test and post-test.

Timepoint

T0 (Pre-test): Before the interventionT1 (Post-test): Immediately after the interventionThe outcome scores will be treated as continuous variables and analyzed using appropriate statistical methods (e.g., repeated measures ANOVA or linear mixed models) to evaluate both within-group and between-group differences.

Method of measurement

Spitzer's 7-item generalized anxiety disorder scale. Rees et al.'s anxiety sensitivity scale. Questionnaire of metacognitions and positive meta-emotions. Self-administered Vakirios Ambivalence Questionnaire

2

Description

Positive metacognitions and meta-emotions refer to an individual's beliefs about the usefulness or positive consequences of cognitive and emotional processes, especially when facing challenging situations. This variable includes evaluation of one's mental performance, the value of positive thoughts and emotions, and perceived control over them. This construct plays an important role in emotional regulation, coping styles, and vulnerability to psychological disorders. In this study, it will be assessed using the Positive Metacognitions and Meta-Emotions Questionnaire (Beer & Moneta, 2010).

Timepoint

T0 (Pre-test): Before the interventionT1 (Post-test): Immediately after the interventionThe outcome scores will be treated as continuous variables and analyzed using appropriate statistical methods (e.g., repeated measures ANOVA or linear mixed models) to evaluate both within-group and between-group differences.

Method of measurement

Positive metacognitions and meta-emotions will be measured using the Positive Metacognitions and Meta-Emotions Questionnaire (PMCEQ; Beer & Moneta, 2010). This 18-item self-report scale uses a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). Items in the first factor (irrational positive beliefs) are reverse-scored. The questionnaire comprises three subscales: (a) confidence in positive thoughts, (b) regulation of positive emotions, and (c) irrational positive beliefs. It will be administered at two timepoints: pre-intervention and post-intervention. Data will be analyzed as continuous variables.

3

Description

Self-ambivalence refers to the simultaneous experience of conflicting thoughts, emotions, and beliefs about oneself, often characterized by internal conflict and uncertainty regarding one's self-worth or moral values. This construct reflects cognitive and emotional inconsistencies in self-evaluation and is more prevalent among individuals with anxiety disorders. In this study, self-ambivalence will be measured using the Self-Ambivalence Questionnaire developed by Barr and Karius (2007).

Timepoint

T0 (Pre-test): Before the interventionT1 (Post-test): Immediately after the interventionThe outcome scores will be treated as continuous variables and analyzed using appropriate statistical methods (e.g., repeated measures ANOVA or linear mixed models) to evaluate both within-group and between-group differences.

Method of measurement

Self-ambivalence will be measured using the Self-Ambivalence Questionnaire (Barr & Karius, 2007), which contains 19 items rated on a 5-point Likert scale (0 = not at all to 4 = completely agree). The total score ranges from 0 to 76, with higher scores indicating greater ambivalence. The scale includes two subscales: ambivalence about self-worth and moral ambivalence. It will be administered at two timepoints (pre- and post-intervention), and data will be analyzed as continuous variables.

Secondary outcomes

empty

Intervention groups

1

Description

Participants in this group will receive 10 sessions of unified transdiagnostic group psychotherapy. Each session will last 60 minutes, held weekly and in-person. The content includes integrated cognitive-behavioral techniques targeting shared processes across emotional disorders, such as worry, avoidance, and emotion regulation. The intervention will be delivered by a trained psychotherapist.

Category

Behavior

2

Description

Intervention group: Participants in this group will attend 12 sessions of group-based compassion-focused therapy. Sessions are held weekly, in-person, and each lasts 60 minutes. The intervention is based on Gilbert’s model and includes practices related to acceptance, self-kindness, reducing self-criticism, and mindfulness. Sessions will be led by a trained therapist in compassion-focused therapy

Category

Behavior

3

Description
Control group: Participants in this group will not receive any intervention during the study period. After the completion of the study, they will be offered the opportunity to receive similar therapeutic services if they wish.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr House Counseling Center
Full name of responsible person
Dr. Afsana Kandaharizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Phone
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Email
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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
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Faezeh Bahri
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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

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

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

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

Data Dictionary

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