Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of the Unified Protocol for Transdiagnostic Treatment on Symptoms and Psychological Indicators of University Students with Health Anxiety Comorbid with Other Emotional Disorders: A Randomized Controlled Trial

Protocol summary

Study aim

The present study is designed as a clinical trial to examine the effectiveness of unified transdiagnostic therapy on psychological indices (rumination, body awareness, experiential avoidance, and distress tolerance) among students with health anxiety comorbid with other emotional disorders.

Design

Thirty-two participants with health anxiety comorbid with emotional disorders will be randomly assigned (using the minimization method) in a double-blind manner to the treatment and control groups.

Settings and conduct

The assignment of participants will be carried out by an individual other than the therapist. The minimization randomization method will be used for participant allocation. Referrals to the treatment and waiting list groups will be made by the University of Kurdistan Counseling Center and mental health specialists.

Participants/Inclusion and exclusion criteria

Students diagnosed with health anxiety at the University of Kurdistan in the year 1404 (2025-2026) constitute the overall population of the study. The sample group includes a number of individuals with health anxiety comorbid with emotional disorders.

Intervention groups

Individuals with health anxiety comorbid with emotional disorders will be randomly assigned to two groups: the unified transdiagnostic treatment group and the waiting list control group.

Main outcome variables

Health anxiety, Anxiety and Depression, Distress Tolerance, Experiential Avoidance, Rumination, Body awarness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250530065973N1**
Registration date: **2025-06-20, 1404/03/30**
Registration timing: **prospective**

Last update: **2025-06-20, 1404/03/30**
Update count: **0**

Registration date

2025-06-20, 1404/03/30

Registrant information

Name
Elham Fathi
Name of organization / entity
The University of Kurditan
Country
Iran (Islamic Republic of)
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+98 87 3872 1255
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-26, 1404/04/05

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of the Unified Protocol for Transdiagnostic Treatment on Symptoms and Psychological Indicators of University Students with Health Anxiety Comorbid with Other Emotional Disorders: A Randomized Controlled Trial

Public title
The Effectiveness of the Unified for Transdiagnostic Treatment on Health Anxiety Comorbid with other Emotional Disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The Diagnosis of Health Anxiety Disorder is based a Clinical Interview and the Health Anxiety Questionnaire. Having at least one Emotional Disorder. Providing informed consent to participate in the study. The ability to speak Persian. Participants must be at least 18 years old.

Exclusion criteria:
Receiving concurrent psychological treatment. Having other psychiatric disorder. The need for pharmacological intervention. Being absent from more than two therapy sessions.

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
After selection based on the inclusion and exclusion criteria, participants will be assigned to the treatment and control groups using the minimization method. This approach ensures balanced distribution of gender across groups: for instance, if the first participant is female, she will be placed in the first group. If the second participant is male, he will also be placed in the first group. Conversely If the third participant is female, she will be placed in the second group. This process continues to ensure gender variables are evenly distributed between the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, clinical interviews to assess inclusion and exclusion criteria will be conducted by a licensed clinical psychologist. After providing full information about the aims and procedures of the study, written informed consent will be obtained from all participants. Participants will be randomly assigned to intervention and control groups by an independent individual who will not be involved in treatment or assessments. They will be blinded to their group assignment and will only be informed about the general purpose of the study. The treating clinician will also remain unaware of group allocation, and the intervention sessions will be delivered without knowledge of whether the participant is in the intervention or control group.Outcome assessments at pre-test, post-test, and one-month follow-up, as well as data analysis, will be conducted by independent researchers who will be blinded to group allocation. Therefore, blinding will be implemented at the levels of participants, clinical provider, and outcome assessors/data analysts, and all ethical standards for human subject research will be fully respected.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee for Biomedical Research University of Kurdistan

Street address
Pasdaran Boulevard, University of Kurdistan, Central Administration

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Approval date
2025-05-17, 1404/02/27

Ethics committee reference number
IR.UOK.REC.1404.019

Health conditions studied

1

Description of health condition studied
Health Anxiety

ICD-10 code
F45.2

ICD-10 code description
Hypochondriacal disorders

Primary outcomes

1

Description
Health Anxiety
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_ up
Method of measurement
Salkovskis et al. Health Anxiety Questionnaire

2

Description
Dpression
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_ up
Method of measurement
Beck Depression Inventory(BDI)

3

Description
Anxiety
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_ up
Method of measurement
Beck Anxiety Inventory(BAI)

Secondary outcomes

1

Description
Distress Tolerance
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_
Method of measurement
Distress and Tolerance Scale (DTS) by simons and Gaher

2

Description
Experiential Avoidance
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_
Method of measurement
Gamez Eexperiential Questionnare (EAAQ)

3

Description
Rumination
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_
Method of measurement
Ruminative Responses Scale(RRS) Nolen_ Hoeksema

4

Description
Body Awareness
Timepoint
pre_ Treatment, post_ Treatment, and one_ month Follow_
Method of measurement
Body Awareness Questionnaire (BAQ) by shields et al

Intervention groups

1

Description
Intervention group: The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders consists of up to twelve 45-minute sessions. This treatment targets and modifies emotional experiences through enhancing emotional awareness and cognitive flexibility, identifying and replacing maladaptive emotional behaviors with more adaptive ones, recognizing and preventing emotional avoidance, increasing awareness of and exposure to physical sensations, and facilitating emotional exposure in relevant situations.
Category
Treatment - Other

2

Description
Control group: The control group will be placed on a waiting list to receive the Unified Transdiagnostic Treatment. After the completion of the follow-up sessions for the intervention groups, the same treatment protocol will be offered to the control group, identical to the one provided to the initial intervention group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Kurdistan Counseling Center
Full name of responsible person
Anvar Dastbaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Kurdistan
Full name of responsible person
Ali Akbar Mozafari
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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
University of Kurdistan
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
University of Kurdistan
Full name of responsible person
Elham Fathi
Position
Master' Student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

A portion of the data, including information related to the primary outcome, is available for sharing.

When the data will become available and for how long

Data access will be granted one year following the publication of the study results.

To whom data/document is available

The data will be available only to researchers affiliated with academic institutions.

Under which criteria data/document could be used

Requests for data use are permitted only for cross-cultural research or meta-analytic studies.

From where data/document is obtainable

Researchers may request the relevant documents or data by contacting the following email address: nasiri.uok@yahoo.com

What processes are involved for a request to access data/document

Data will be provided via email or in person after the request has been reviewed and approved.

Comments