Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the Effectiveness of the Unified Protocol for Transdiagnostic Treatment (UP) and Cognitive Behavioral Therapy (CBT) on Emotional, Behavioral and Cognitive Components in Patients with Illness Anxiety Disorder Comorbid with Depression

Protocol summary

Study aim

The aim of the study is to compare the effectiveness of the Unified Protocol for Transdiagnostic Treatment and Cognitive Behavioral Therapy (CBT) on cognitive, behavioral and emotional components in patients with illness anxiety disorder comorbid with depression.

Design

This research compares two groups receiving unified transdiagnostic treatment and the group receiving cognitive-behavioral therapy. The sample includes 50 patients with an illness anxiety disorder who are selected as available and randomly assigned to intervention groups.

Settings and conduct

After the invitation was presented at Rasoul Akram Hospital in Tehran city, 50 eligible patients were randomly divided into two groups after explaining the treatment and obtaining informed consent. Then a pre-test and a post-test are conducted after the intervention and the subjects of both groups are followed up three months later. This study will be conducted in a double-blind manner, which means that the type of treatment will be unknown to the patients and the data analyst. Participants will also be unaware of which group they belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primary diagnosis of illness anxiety disorder, presence of a comorbid diagnosis of major depressive disorder (MDD) and/or persistent depressive disorder (PDD) based on DSM-5 criteria; Exclusion criteria: receiving psychological treatments in the last 3 years.

Intervention groups

This study has two intervention groups. In the first group, in order to check the effectiveness of the unified transdiagnostic treatment method, Barlow's new unified transdiagnostic treatment protocol is used. Patients in the second group receive the treatment protocol called "cognitive-behavioral therapy for disease anxiety". Both protocols are 12 weekly sessions for 60-90 minutes.

Main outcome variables

Health anxiety symptoms and Beck depression symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170104031765N2**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2024-01-21, 1402/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of the Unified Protocol for Transdiagnostic Treatment (UP) and Cognitive Behavioral Therapy (CBT) on Emotional, Behavioral and Cognitive Components in Patients with Illness Anxiety Disorder Comorbid with Depression

Public title
Comparison of the Effectiveness of the Unified Protocol for Transdiagnostic Treatment and Cognitive Behavioral Therapy (CBT) in Improving Severe Health Anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primary diagnosis of illness anxiety disorder according to the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) Diagnosis of major depressive disorder (MDD), persistent depressive disorder (PDD) based on DSM-5 criteria Ages 18 to 65 years Able to read and write Not taking psychiatric drugs or in the case of taking antidepressants and anti-anxiety drugs for at least two months before the onset of interventions, the drug dose must be constant and the patient must agree to the drug dose remaining constant during the study
Exclusion criteria:
Patients with psychotic disorders Patients with bipolar disorder Patients with depressive disorder with psychotic symptoms Patients with a history of drug use in the last 6 months Patients at risk of suicide Personality disorder making the treatment procedure very difficult Patients with eating disorders Having a history of incurable physical illness such as cancer The need to change, stop or increase the drug dose or start a new drug after pre-test evaluations Receiving other psychological treatments in the past 5 years
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 50 people are selected according to similar research, in an accessible way. Then random replacement is done by lottery method (one number will be assigned to each sample person). We write down the numbers on paper, fold them and put them in a container. We mix and stir the papers completely. Then we take out the papers one by one and put one number in the first group and one number in the second group. Then random application will be done. In this way, one group is known as "cognitive behavioral therapy group" and the other group is known as "Unified transdiagnostic therapy group". The lottery will be done by putting the two groups obtained from the previous step (random replacement step) into two separate envelopes and placing them in a container. Then we randomly take one envelope out of the container and assign it to the "Unified transdiagnostic treatment group" and the other envelope to the "cognitive behavioral therapy group".
Blinding (investigator's opinion)
Double blinded
Blinding description
Our study will be conducted in a double-blind manner, which means that the type of treatment was unknown to the patients and the data analyst. Participants will not know the group type. Also, at first, they will be unaware of which group they belong to. The questionnaires will be completed under the supervision of an individual unaware of the research objectives.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-11-12, 1402/08/21
Ethics committee reference number
IR.IUMS.REC.1402.676

Health conditions studied

1

Description of health condition studied
illness anxiety disorder
ICD-10 code
F45.2
ICD-10 code description
Hypochondriacal disorders

Primary outcomes

1

Description
Health anxiety score in Salkowski questionnaire
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Health Anxiety Questionnaire - Short Form (SV-HAI)

2

Description
Depression score in Beck questionnaire
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Beck Depression Inventory - Second Edition (BDI-II)

Secondary outcomes

1

Description
The score of cognitions related to health anxiety
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Health Cognition Questionnaire (HCQ)

2

Description
Anxiety Sensitivity Score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Anxiety sensitivity index-3 (ASI-3)

3

Description
Distress Tolerance Score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Distress Tolerance Scale (DTS)

4

Description
Emotion Regulation Score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Emotion regulation Questionnaire (ERQ)

5

Description
Beck anxiety score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Beck Anxiety Inventory (BAI)

6

Description
Cyberchondria Score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Short-Form- Cyberchondria Severity Scale (12-CSS)

7

Description
Score different aspects of illness behavior
Timepoint
Before and after interventions and three month follow-up
Method of measurement
The Scale for the Assessment of Illness Behaviour (SAIB)

8

Description
Interoceptive Attention Score
Timepoint
Before and after interventions and three month follow-up
Method of measurement
Interoceptive Attention Scale

9

Description
Amount of credibility/expectancy of improvement
Timepoint
After interventions
Method of measurement
Credibility/Expectancy Questionnaire (CEQ)

10

Description
The rate of therapeutic alliance
Timepoint
After interventions
Method of measurement
Working Alliance Inventory (WAI) For assessing therapeutic alliance

Intervention groups

1

Description
Intervention group: the people of the experimental group or integrated meta-diagnostic therapy group during 12 group sessions of approximately 60 to 90 minutes. All sections are performed on the subjects in a fixed order and with equal sessions. The sessions of this treatment protocol include the first session: increasing motivation; The second session: Providing psychological training; The third and fourth sessions: Emotional awareness training; The fifth session: cognitive reassessment; The sixth session: Identifying avoidance patterns; the Seventh session: Emotion-induced behaviors (EDBs); Eighth session: awareness and tolerance of physical feelings; 9th and 11th sessions: introception and situational expouser and 12th session: relapse prevention. Treatment sessions will also be offered to clients by targeting treatment goals and focusing on different parts of the protocol.

Category
Treatment - Other

2

Description
Control group: Patients assigned to the control group receive the treatment protocol called "cognitive-behavioral therapy for illness anxiety". This protocol consists of 12 weekly sessions for 60-90 minutes, and was designed by Axelsson in 2020 based on the cognitive-behavioral model. The content of the cognitive-behavioral therapy sessions is as follows. The first session: Introduction to CBT and health anxiety. Second session: The CBT model of health anxiety. The third session: Interoceptive exposure. Fourth session: Response prevention. Fifth session: Exposure in vivo. The sixth session: Imaginal exposure. Seventh session: Continued imaginal exposure and the fear of death. Eighth session: Common obstacles to exposure. 9th and 10th session: Continued exposure and response prevention. The eleventh session: summary and values. Session 12: Continuous improvement and healthcare utilization.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Rasoole Akram Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran
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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
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Hamid Mohsenabadi
Position
PhD student
Latest degree
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Other areas of specialty/work
Psychology
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Person responsible for updating data

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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