

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Symptom and Emotion Regulation in Patients With Generalized Anxiety Disorder

Protocol summary

Study aim

The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Symptom and Emotion Regulation in Patients With Generalized Anxiety Disorder

Design

Semi-experimental research design, pre-test and post-test, two-tiered, twenty patients, randomly divided into two experimental and control groups, each with 10 patients

Settings and conduct

The diagnosis was made by a psychiatrist. Psychotherapy was performed by a clinical psychologist. Patients entered the treatment groups with satisfaction and using random numbers table. Anxiety, depression, worry and emotional regulation questionnaires were administered to the two groups. Pre-test and post-test were performed on both groups. The control group received no intervention. Experimental approach was used in the experimental group. The approach was individual.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being resident in Sanandaj; Having generalized anxiety disorder criterion; Having motivation and satisfaction for attending in sessions; level of education: at least high school diploma; Exclusion criteria: Diagnosis of any comorbid disorders (except for anxiety and depression); having major depressive disorder; having psychotic symptoms and drug abuse and suicidal thoughts: having all symptoms of personality disorders.

Intervention groups

Experimental approach was used in the intervention group individually. The control group received no intervention. both groups received medication therapy.

Main outcome variables

Anxiety and depression and worry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100614004178N3**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

Abolfazl Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 5541 9151

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-26, 1397/01/06

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Symptom and Emotion Regulation in Patients With Generalized Anxiety Disorder

Public title

The Efficacy of Unified Transdiagnostic Therapy in Reducing Worry, Anxiety, Depressive Symptom and Emotion Regulation in Patients With Generalized Anxiety Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being resident in sanandaj) Having generalized anxiety disorder symptoms based on psychiatric or clinical psychologists diagnosis according to SCID-1 Having motivation and satisfaction for attending in treatment sessions level of education :Having at least high school diploma

Exclusion criteria:

diagnosis of any comorbid disorders except for anxiety and depression which has been mentioned in the research having major depressive disorder (MDD) having psychotic symptoms and drug abuse and suicidal thoughts having all symptoms of personality disorders according to DSM-5

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be divided into two experimental and control groups using simple random sampling using sealed envelopes. This will provide 20 envelopes with 10 letters on the letter A (the intervention group) and 10 letters on the cards B (control group) and put in the envelope. The envelopes will be mixed together and randomly one of the envelopes will be selected by the patient and assigned to one of the groups accordingly.

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 Kurdistan University of Medical Sciences

Street address

Ave., Nahid4., Street Sharifabad

City

Sanandaj

Province

Kurdistan

Postal code

۶۶۱۷۹۳۴۵۸۴

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.MUK.REC.1396.5008

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

anxiety score in beck anxiety inventory

Timepoint

pre and post treatment and after 1month follow up

Method of measurement

beck depression inventory 2, beck anxiety inventory,

Secondary outcomes

1

Description

Anxiety

Timepoint

pre and post treatment and after 3 month follow up

Method of measurement

Beck anxiety inventory

2

Description

depression

Timepoint

pre and post treatment and after 3 month follow up

Method of measurement

beck depression inventory

3

Description

worry

Timepoint

pre and post treatment and after 3 month follow up

Method of measurement

Pennsylvania worry questionnaire

4

Description

emotion regulation

Timepoint

pre and post treatment and after 3 month follow up

Method of measurement

difficulties in emotion regulation questionnaire

Intervention groups

1

Description

Intervention group: En Experimental was participated in transdiagnostic therapy at 8-12 weeks for 1 hours. Therapeutic components of transdiagnostic therapy were including: home work, Positive and Negative Feedback, Summary, Three-System Thriller Model, Emotional Components, Cognitive Distortions, Automatic Thoughts, Ingestion PracticeThinking, Downward Arrow, Dysfunctional Attitude Classification, LogicalAnalysis, Analysis of the Utility of Beliefs./ Pre-test and finally post-test were performed on the experimental group

Category

Treatment - Other

2

Description

Control group: In the control group, there was no intervention,Pre-test and post-test were performed on control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sanandaj Welfare Psychological Center

Full name of responsible person

Shelir Kolahzari

Street address

Safari St.

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Province

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6618654658

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shelir Kolahzari

Full name of responsible person

Shelir Kolahzari

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Sharif Abad Street

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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

Shelir Kolahzari

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shelir Kolahzari

Full name of responsible person

Shelir Kolahzari

Position

Mental Health

Latest degree

Master

Other areas of specialty/work

Psychology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University of Medical Science
Full name of responsible person
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Position
M.A
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

dissemination of patient information is not necessary

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

original article in journal

When the data will become available and for how long

after 6month post treatment

To whom data/document is available

report is accessible for researchers

Under which criteria data/document could be used

researcher in this field

From where data/document is obtainable

corresponding author

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

via email request

Comments