

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the efficacy of pharmacotherapy and combination of pharmacotherapy with transdiagnostic cognitive-behavior therapy on anxiety and depression symptoms in patients with emotional disorders

Protocol summary

Study aim

Determine the effectiveness of pharmacotherapy and combination of pharmacotherapy with transdiagnostic cognitive-behavior therapy on anxiety and depression symptoms in patients with emotional disorders

Design

Practical and semi-experimental data collection is pre-test, post-test and follow up with control group. Clinical trial with control group, not blind, sample selection available targeted. Experimental group was 14 and control group was 15

Settings and conduct

The treatment room of the Kurdistan University Meetings weekly for one hour for each client At each session, specific psychological techniques were practiced with clients at each session

Participants/Inclusion and exclusion criteria

The criteria for entering , at least 18 years of age, male and female gender, diagnosis of anxiety disorder and depression. According to the psychiatrist, Sanandaj resident, No substance use, the willingness to participate and not receiving any therapeutic interventions, including psychological and Medication at least in the last year. Exclusion criteria, the occurrence of other psychiatric disorders, one and two, except emotional disturbances, the risk of suicide.

Intervention groups

The experimental group received the transdiagnostic treatment with the drug, which included eight sessions of 50 to 60 minutes per week. The control group received only medication.

Main outcome variables

anxiety and depression.

General information

Reason for update

In the English title the name of the treatment was mistaken for the meta-cognitive meta-diagnosis.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181019041385N1**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **retrospective**

Last update: **2020-01-12, 1398/10/22**

Update count: **1**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Pegah Ommati

Name of organization / entity

The University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 9922

Email address

pegahommati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the efficacy of pharmacotherapy and combination of pharmacotherapy with transdiagnostic cognitive-behavior therapy on anxiety and depression symptoms in patients with emotional disorders

Public title

Comparision of the efficacy of pharmacotherapy and combination of pharmacotherapy with transdiagnostic cognitive-behavior therapy on anxiety and depression symptoms in patients with emotional disorders

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Anxiety Disorder and Comorbid Depression (According to Psychiatrist) Sanandaj resident No history of substance abuse The desire to participate and not receive any therapeutic intervention, including psychological and medication, at least in the last year

Exclusion criteria:

Has personality disorders A history of suicide illiterate

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **29**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

www.iranduc.ir

Secondary trial Id

1426565

Registration date

2018-05-21, 1397/02/31

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of kurdestan

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.UOK.REC.1398.023

Health conditions studied

1

Description of health condition studied

Anxiety disorders and complex depression

ICD-10 code

F41.3

ICD-10 code description

Anxiety disorders and complex depression

Primary outcomes

1

Description

Anxiety

Timepoint

pre test, post test and follow up(one month after treatment)

Method of measurement

Beck Anxiety Inventory

2

Description

Depression

Timepoint

pre test, post test and follow up(one month after treatment)

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

emotional regulation

Timepoint

Before and after 8 sessions of treatment

Method of measurement

Use the emotion regulation difficulty questionnaire

2

Description

Negative repetitive thoughts

Timepoint

Before and after 8 sessions of treatment

Method of measurement

Using Negative repetitive Thought Questionnaire

3

Description

Intolerance of Uncertainly

Timepoint

Before and after 8 sessions of treatment

Method of measurement

Use of uncertainty intolerance questionnaire

4

Description

Anxiety Sensitivity

Timepoint

Before and after 8 sessions of treatment

Method of measurement

Anxiety Sensitivity Questionnaire

5

Description

Experiential Avoidance

Timepoint

Before and after 8 sessions of treatment

Method of measurement

Experiential Avoidance Questionnaire

Intervention groups

1

Description

In the present study, participants were taking Anti-anxiety and antidepressant medication (Such as serotonin, Clonazepam, Buspirone, and venlafaxine) and also received eight sessions of transdiagnostic cognitive-behavioral therapy. Session 2: Psychological Training and Emotion Recognition. Session 3: Emotional Awareness Training. Session 4: Cognitive Assessment and Reassessment. Session 5: Emotional Avoidance (Behavior Understanding). Session 6: Emotional Behavior Behaviors (EDBs) Session 7: Exposure to Physical Sensations.

Category

Treatment - Other

2

Description

Control group: only anti-anxiety and anti-depressant drugs they consume.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods Hospital

Full name of responsible person

Hamid Moetasemi

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

2

Recruitment center

Name of recruitment center

Kurdistan Welfare Center

Full name of responsible person

Hamid Moetasemi

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

3

Recruitment center

Name of recruitment center

Kurdistan University Counseling Center

Full name of responsible person

Ahmad Amani

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

4

Recruitment center

Name of recruitment center

Khanevadeh Clinic

Full name of responsible person

Asrin Seiedolshohadai

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

5

Recruitment center

Name of recruitment center

Psychiatry office

Full name of responsible person

Farzin Rezaei

Street address

Plate 42. Alborz Golbarg Seven. Keshavar St. Khanqah St.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of kurdestan

Full name of responsible person

Mehdi Zemestani

Street address

plate. 42, Keshavarz Ave., Khaneghah Ave.

City

Sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The university of kurdestan

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

the university of kurdestan

Full name of responsible person

mehdi zemestany

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Seven Plateau 42, Khaneghah Alley, Keshavarz Ave.

City

sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

m.zemestan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Kordestan

Full name of responsible person

mehdi zemestani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Kurdistan University, Pasdaran Boulevard, Sanandaj.Iran

City

SANANDAJ

Province

Kurdistan

Postal code

6617715175

Phone

00968733664600_8 ((۲۲۴۶) داخلی)

Email

m.zemestan@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

the university of kurdestan

Full name of responsible person

pegah ommati

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Seven Plateau 42, Khaneghah Alley, Keshavarz Ave.

City

sanandaj

Province

Kurdistan

Postal code

6619653814

Phone

+98 87 3323 9922

Email

pegahommati@yahoo.com

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

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

Title and more details about the data/document

The data will be provided after it is completed.

When the data will become available and for how long

Information will be provided up to 5 months after the defense.

To whom data/document is available

Under the guidance of the supervisor, information will be provided.

Under which criteria data/document could be used

For the scientific use and promotion of knowledge.

From where data/document is obtainable

From the Supervisor Dr. Mehdi zemestany.

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

Information will be provided up to 5 months after the defense.

Comments