

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The comparison of efficacy of primary transdiagnostic protocol based on repetitive negative thinking with Barlow transdiagnostic protocol (2011) in symptoms reduction of people with co-occurrence anxiety and depression disorders.

Protocol summary

Summary

(1) Objectives: A) To determine pilot efficacy of primary transdiagnostic protocol based on repetitive negative thinking on three person with co-occurrence anxiety and depression disorders; B) To compare efficacy of primary transdiagnostic protocol based on repetitive negative thinking with Barlow transdiagnostic protocol (2011) in symptoms reduction of patients with co-occurrence anxiety and depression disorders. (2) Design: General plan of this study is consisted of experimental pre-test and post-test with control group and follow-up period. (3) Setting and conduct: In the beginning, primary transdiagnostic protocol based on repetitive negative thinking was designed. Then, in order to pilot efficacy of primary protocol, it will be carried out on three patients with co-occurrence anxiety and depression disorders. After pilot study, samples will be selected then they will be randomly assigned to research groups. Assessment of the tools used in research will be performed by a trained assessor other than the researcher in three steps of before treatment, at the end of treatment, and after a 2-month follow-up. At the end, desired treatments will be individually carried out on research sample. (4) Participants: The research sample is consisted of 45 patients with co-occurrence anxiety and depression disorders that will be selected from undergraduate students referred to counseling and psychological services center of Sharif University. They will be randomly assigned to three experimental and control group. (15 participants in experimental group 1, 15 participants in experimental group 2 and 15 peoples in control group or wait-list group). (5) Intervention: The first intervention is consisted of 12 sessions (each session is 45 minutes in a week) of transdiagnostic therapy based on repetitive negative thinking for experimental group 1. The second intervention is

consisted of 12 sessions (each session is 45 minutes in a week) of Barlow transdiagnostic protocol (2011) for experimental group 2. (6) Main outcome measures: main outcome measures variables in this research are anxiety, depression, repetitive negative thinking, emotional dysregulation, metacognitive beliefs and experiential avoidance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090414564N1**

Registration date: **2013-12-29, 1392/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-29, 1392/10/08

Registrant information

Name

Mehdi Akbari

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 6602 1735

Email address

akbari.psy@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahed University

Expected recruitment start date

2013-11-11, 1392/08/20

Expected recruitment end date

2014-01-10, 1392/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy of primary transdiagnostic protocol based on repetitive negative thinking with Barlow transdiagnostic protocol (2011) in symptoms reduction of people with co-occurrence anxiety and depression disorders.

Public title

The comparison of efficacy of primary transdiagnostic protocol based on repetitive negative thinking with Barlow transdiagnostic protocol in symptoms reduction of people with co-occurrence anxiety and depression disorders.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: Having diagnostic criteria more than one co-occurrence anxiety and depression disorders based on structural clinical interview for axis I; Undergraduate student; Patient consent for participate in research; The availability of the patient during treatment and follow-up period; Stable on the same dose if use psychotropic medications. Exclusion criteria: Having any kind of psychosis disorder; Having bipolar mood disorder (type I or II); Having any kind of severe personality disorder; The history of drug abuse; giving another psychological treatment, such as cognitive behavior therapy, behavior therapy, cognitive therapy or group therapy simultaneous with treatment or in past; Having serious problem in during the study such as suicidal thoughts or change in rates of psychotropic medications dose.

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **45****Randomization (investigator's opinion)**

Randomized

Randomization description**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 Shahed University

Street address

Shahed University, Tehran- Gom freeway, Opposite Holy Shrine of Imam Komeini, Tehran, Iran

City

Tehran

Postal code

3319118651

Approval date

2013-11-11, 1392/08/20

Ethics committee reference number

41/185117

Health conditions studied**1****Description of health condition studied**

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

2**Description of health condition studied**

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

3**Description of health condition studied**

Post-traumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder

4**Description of health condition studied**

Social phobia disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobia disorder

5

Description of health condition studied

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder

6

Description of health condition studied

Major depressive disorder

ICD-10 code

F33

ICD-10 code description

Recurrent depressive disorder

Primary outcomes

1

Description

Repetitive negative thinking

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Repetitive Negative Thinking Questionnaire

2

Description

Anxiety

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Depression Anxiety Stress Scale-21

3

Description

Depression

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Depression Anxiety Stress Scale-21

4

Description

Emotional dysregulation

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Difficulties in Emotion Regulation Scale

5

Description

Metacognition beliefs

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Metacognition Beliefs Questionnaire

6

Description

Experiential avoidance

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

The Multidimensional Experiential Avoidance Questionnaire

Secondary outcomes

1

Description

General function

Timepoint

Before treatment, at the end of treatment, and after a 2-month follow-up

Method of measurement

Work and Social Adjustment Scale

Intervention groups

1

Description

The first intervention is consisted of 12 sessions (each session is 45 minutes in a week) of transdiagnostic therapy based on repetitive negative thinking for experimental group 1.

Category

Behavior

2

Description

The second intervention is consisted of 12 sessions (each session is 45 minutes in a week) of Barlow transdiagnostic therapy (2011) for experimental group 2.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling and Psychological Services Center of Sharif University

Full name of responsible person

Mitra Aghajani

Street address

Counseling and Psychological Services Center, Sharif University, Azadi Street, Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University

Full name of responsible person

Dr.kiasalari

Street address

Shahed University, Tehran- Gom freeway, Opposite Holy Shrine of Imam Komeini, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mehdi Akbari

Position

Doctoral Candidate in Clinical Psychology

Other areas of specialty/work

Street address

Shahed University, Tehran- Gom freeway, Opposite Holy Shrine of Imam Komeini, Tehran, Iran

City

Tehran

Postal code

3319118651

Phone

+98 21 6602 1735

Fax

Email

Akbari.psy@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mehdi Akbari

Position

Doctoral Candidate in Clinical Psychology

Other areas of specialty/work

Street address

Shahed University, Tehran- Gom freeway, Opposite Holy Shrine of Imam Komeini, Tehran, Iran

City

Tehran

Postal code

3319118651

Phone

+98 21 6602 1735

Fax

Email

Akbari.psy@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mehdi Akbari

Position

Doctoral Candidate in Clinical Psychology

Other areas of specialty/work

Street address

Shahed University, Tehran- Gom freeway, Opposite Holy Shrine of Imam Komeini, Tehran, Iran

City

Tehran

Postal code

3319118651

Phone

+98 21 6602 1735

Fax

Email

Akbari.psy@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty