

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The clinical trial of the comparison of Transdiagnostic Therapy with cognitive- behavior therapy on emotion regulation strategies in patients with emotional disorders

Protocol summary

Summary

An important concept for understanding emotional disorders is emotion regulation. The present study focuses on Effectiveness of Transdiagnostic Therapy on emotion regulation strategies of patients with emotional disorders in comparison with cognitive-behavior therapy. This study was a pretest/post test randomized control trial. Inclusion criteria was age 18 or older; be fluent in Persian; be able to attend all treatment sessions and assessments and provide informed consent and exclusion criteria was evidence of dementia or other neuro-cognitive conditions that impair ability; have clinical conditions that require immediate treatment; suicidality; substance use disorders. A diagnostically heterogeneous clinical sample of 23 patients with a principal depression and anxiety disorders that randomly assigned in two groups (transdiagnostic and CBT), and participated in eight sessions. Participants were recruited from Clinical Psychology and Psychiatry Clinics of Taleghani Hospital, Tehran, Iran. Cognitive Emotion Regulation Questionnaire (CERQ) and Positive and Negative Affect Scale (PANAS) were completed pre and post intervention by participants. The results were analyzed by dependent sample t test and analyses of covariance (ANCOVA). Data analysis showed that transdiagnostic therapy resulted in significant improvement of cognitive emotion regulation strategies. Transdiagnostic treatment was confirmed in decreasing negative affects and negative cognitive emotion regulation strategies and improving positive affect and positive cognitive emotion regulation strategies in patients with depression and anxiety disorders, and was more effective than cognitive-behavior therapy for increased positive affects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010516085N1**

Registration date: **2014-03-13, 1392/12/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-13, 1392/12/22

Registrant information

Name

mozghan lotfi

Name of organization / entity

shahid beheshti university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Medicine School of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-07-09, 1391/04/19

Expected recruitment end date

2013-01-08, 1391/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of the comparison of Transdiagnostic Therapy with cognitive- behavior therapy on emotion regulation strategies in patients with emotional disorders

Public title

The clinical trial of the comparison of Transdiagnostic Therapy with cognitive- behavior therapy on patients with depression and anxiety disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 or older; be fluent in Persian; be able to attend all treatment sessions and assessments; provide informed consent Exclusion criteria: have evidence of dementia or other neuro-cognitive conditions that impair ability; have clinical conditions that require immediate treatment; suicidality; substance use disorders

Age

From **22 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

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**

Deputy of Research of Medicine School of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Koodakayar Avenue. Evin. Tehran, Iran

City

Tehran

Postal code**Approval date**

2013-01-08, 1391/10/19

Ethics committee reference number

0308/14024

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

anxiety disorders and depression

ICD-10 code

f32.1, f41

ICD-10 code description

generalized anxiety disorder, moderate depressive episode

Primary outcomes**1****Description**

anxiety

Timepoint

at the end of treatment

Method of measurement

by questionnaire

Secondary outcomes**1****Description**

depression

Timepoint

at the end of treatment

Method of measurement

by questionnaire

Intervention groups**1****Description**

Treatment in the transdiagnostic condition consisted of 8 weekly 45 minute sessions following unified protocol. The unified protocol consists of five core treatment modules: (a) increasing present-focused emotion awareness (b) increasing cognitive flexibility (c) identifying and preventing emotion sensations and (e) emotion-focused exposure (Allen, McHugh, & Barlow, 2008; Barlow, Ellard, et al., 2011). The first session was focused on motivation enhancement for treatment engagement and change. The second session emotional understanding was focused, and the third session cognitive reappraisals were trained. The focus of fourth and fifth sessions was emotional avoidance and emotion-focused behaviors. And the content of sixth session was awareness and tolerance of physical sensations. The final two sessions was focused on introceptive and situational emotion exposures.

Category
Behavior

2

Description

In the CBT condition, we conducted 8 weekly 45 minute session following cognitive-behavioral diagnosis- specific manuals.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Psychology and Psychiatry Clinics of Taleghani Hospital

Full name of responsible person

Mrs.Mohammadi

Street address

Clinical Psychology Clinic, Taleghani Hospital, Evin Squ, Tehran, Iran

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Medicine School of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs khateri

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Shahid Beheshti University of Medical Sciences

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research of Medicine School of Shahid Beheshti University of Medical Sciences

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

Department of Clinical Psychology, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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Position

Clinical Psychologist

Other areas of specialty/work

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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