

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The applicability and efficacy of Transdiagnostic cognitive behavior therapy on reducing signs and symptoms of Borderline Personality Disorder with co-occurring emotional disorders

#### Protocol summary

##### Summary

The aim of this study, as an outcome/process research, is to examine the applicability and efficacy of Transdiagnostic Cognitive Behavior Therapy on reducing signs and symptoms of Iranian patients with BPD and co-occurring emotional disorders. Inclusion criteria are: a) age above 18, b) Borderline Personality disorder (BPD), and c) another emotional disorder as a comorbid disorder. Exclusion criteria are: a) presence of diagnostic criteria for psychotic disorder/bipolar disorder/ drug abuse or dependency in the time of research, b) risk of imminently suicidal attempt. By purposeful sampling method, six volunteer patients with Borderline Personality Disorder who met in/exclusion criteria, will participate in a multiple baseline experimental single case study. Participants are recruited from Clinical Psychology and Psychiatry Clinics of Taleghani Hospital and Counselling Center of Tehran University, Tehran, Iran. Each participant will complete the Borderline Personality Inventory (BPI), the Difficulties in Emotion Regulation Scale (DERS), the Positive and Negative Scale (PANAS), the Work and Social Adjustment Scale (WASA), the Affective Lability Scale (ALS), the Toronto Alexithymia Scale (TAS) during 3 baseline, 8 treatment modules and 1 follow up assessments sessions. The unified protocol will be carried out for 16-20 weekly 50 minute sessions. The expected conclusion is deduction of BPD and comorbid disorders symptoms and improvement of emotion regulation skills.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110524899N1**

Registration date: **2016-11-10, 1395/08/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-10, 1395/08/20

##### Registrant information

###### Name

Farzane Mohamadi

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences (SBMU)

###### Country

Iran (Islamic Republic of)

###### Phone

+98 93038129162

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

This research is funded by Shahid Beheshti University of Medical Sciences (SBMU).

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-03-20, 1395/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The applicability and efficacy of Transdiagnostic cognitive behavior therapy on reducing signs and symptoms of Borderline Personality Disorder with co-occurring emotional disorders

## Public title

Unified protocol for the transdiagnostic treatment of borderline personality disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria are: a) age above 18, b) Borderline Personality disorder (BPD) based on psychiatric diagnostic interview by psychiatrist and SCID-II by clinical psychologist, and c) another emotional disorder as a comorbid disorder based on psychiatric diagnostic interview by psychiatrist and SCID-I by clinical psychologist. Exclusion criteria are: a) presence of diagnostic criteria for psychotic disorder/bipolar disorder/ drug abuse or dependency in the time of research, b) risk of imminently suicidal attempt.

## 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: **6**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Postal code

IR.SBMU.SM.REC.1394.

#### Approval date

2015-08-25, 1394/06/03

#### Ethics committee reference number

IR.SBMU.SM.REC.1394.26

## Health conditions studied

### 1

#### Description of health condition studied

Borderline personality disorder

#### ICD-10 code

F60.3

#### ICD-10 code description

Emotionally unstable personality disorder

### 2

#### Description of health condition studied

Depression

#### ICD-10 code

F32.1

#### ICD-10 code description

Moderate depressive episode

### 3

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41

#### ICD-10 code description

Other anxiety disorders

## Primary outcomes

### 1

#### Description

Diagnostic Recovery

#### Timepoint

pre-post treatment

#### Method of measurement

SCHID-II

### 2

#### Description

Emotion Regulation

#### Timepoint

pre-post treatment & after each module

#### Method of measurement

Difficulties in Emotion Regulation Scale(DERS)

### 3

#### Description

Alexithymia

#### Timepoint

pre-post treatment

#### Method of measurement

Toronto Alexithymia Scale (TAS-20)

### 4

#### Description

General function

#### Timepoint

pre-post treatment

**Method of measurement**

Work and Social Adjustment Scale (WSAS)

**5**

**Description**

Depression

**Timepoint**

pre-post treatment & after each module

**Method of measurement**

Depression Anxiety Stress Scale -42

**6**

**Description**

Anxiety

**Timepoint**

pre-post treatment & after each module

**Method of measurement**

Depression Anxiety Stress Scale -42

**7**

**Description**

Affect Intensity

**Timepoint**

pre-post treatment

**Method of measurement**

Affect Intensity Measure (AIM)

**8**

**Description**

Affective Lability

**Timepoint**

pre-post treatment

**Method of measurement**

Affective Lability Scale (ALS)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Patients will participate in 16-20 weekly transdiagnostic cognitive behavior treatment sessions.

**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

**2**

**Recruitment center**

**Name of recruitment center**

Counselling center of Tehran University

**Full name of responsible person**

Mrs. Issac

**Street address**

**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

**Street address**

Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Velenjak, 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**

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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farzaneh Mohamadi

**Position**

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**City**

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**Postal code****Phone**

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**Fax****Email****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*