

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effectiveness of dialectical behavioral therapy on perceived stress of ego and cognitive emotion regulation in people with borderline personality disorder (BPD).

#### Protocol summary

##### Study aim

The major objective of this study is to determine the effectiveness of dialectical behavior therapy on perceived stress, ego strength, and cognitive emotion regulation in female patients with a borderline personality disorder.

##### Design

In the first step, a method called "purposive sampling" will be used in this study. In the second step, where the participants will be split into two groups, "experimental" and "control," a random method will be used. This study's statistical sample was gathered in two stages. a) In the first stage, the borderline personality disorder questionnaire and a semi-structured clinical interview and test will be used to find people with a borderline personality disorder. b) In the second stage, 40 people with a borderline personality disorder will be chosen at random and divided into two groups of 20 each (experimental and control groups).

##### Settings and conduct

This study uses a pre-test-post-test design with a control group in a semi-experimental setting. All female patients admitted to Shiraz's Ibn Sina Psychiatric Hospital in 2022 who have a borderline personality disorder and are aged between 20 and 40 will make up the statistical population of this study.

##### Participants/Inclusion and exclusion criteria

women with borderline personality disorder

##### Intervention groups

- Dialectical behavior therapy has a significant effect on perceived stress, ego strength, and cognitive emotion regulation in female patients with a borderline personality disorder.

##### Main outcome variables

Independent variable: Therapeutic behavior (dialectic)  
Dependent variable: Perceived stress, ego strength, and cognitive emotion regulation in borderline personality

disorder patients.

#### General information

##### Reason for update

##### Acronym

BPD

##### IRCT registration information

IRCT registration number: **IRCT20230121057171N1**

Registration date: **2023-02-04, 1401/11/15**

Registration timing: **prospective**

Last update: **2023-02-04, 1401/11/15**

Update count: **0**

##### Registration date

2023-02-04, 1401/11/15

##### Registrant information

##### Name

FATEMEH TOOBAAE

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3233 0988

##### Email address

helentb.5555@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-05, 1401/11/16

##### Expected recruitment end date

2023-03-16, 1401/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effectiveness of dialectical behavioral therapy on perceived stress of ego and cognitive emotion regulation in people with borderline personality disorder (BPD).

**Public title**  
Effectiveness of dialectical behavioral therapy on perceived stress of ego and cognitive emotion regulation in people with borderline personality disorder (BPD).

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
women with borderline personality disorder  
**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**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**

Shiraz University of medical sciences

**Street address**

Unit 3, Garnet building ,38 mirzai shirazi alley, Sanaye square.

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Approval date**

2023-01-10, 1401/10/20  
**Ethics committee reference number**  
IR.SUMS.REC.1401.631

## Health conditions studied

### 1

**Description of health condition studied**

Borderline personality disorder

**ICD-10 code**

F60.3

**ICD-10 code description**

بی ثباتی هیجانی

## Primary outcomes

### 1

**Description**

Independent variable: Therapeutic behavior (dialectic)Dependent variable: Perceived stress, ego strength, and cognitive emotion regulation in borderline personality disorder patients.

**Timepoint**

after 3 months to 6 months

**Method of measurement**

For this research, descriptive statistics tools (SPSS) including tables of frequency, mean, and standard deviation will be used to analyze the data. Afterward, the Multivariate analysis of variance (MANOVA) procedure will also be used to test the hypotheses.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

- Explaining the effectiveness of dialectical behavior therapy on perceived stress dimensions in people with a borderline personality disorder.

**Category**

Behavior

### 2

**Description**

Intervention group: - Explaining the effectiveness of dialectical behavior therapy on the dimensions of ego strength in people with a borderline personality disorder

**Category**

Behavior

### 3

**Description**

Intervention group: - Explaining the effectiveness of dialectical behavior therapy on cognitive emotion

regulation in people with a borderline personality disorder

**Category**

Behavior

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ibn Sina Hospital in Shiraz

**Full name of responsible person**

Jalal kalantaree

**Street address**

Unit 3 ,Garnet building , 38 mirzai shirazi alley,Sanaye square.

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Phone**

+98 935 275 3100

**Email**

helentb.5555@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. mahtab memarpour

**Street address**

Unit3, garnet building ,38 mirzai shirazi alley, Sanaye square.

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Phone**

+98 935 275 3100

**Email**

helentb.5555@gmail.com

**Web page address**

**Grant name**

I do not have

**Grant code / Reference number**

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

No

**Title of funding source**

I do not have government financial resources

**Proportion provided by this source**

1

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh tobaee

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Unit3 , Garnet building , 38 mirzai shirazi alley, Sanaye square.

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Phone**

+98 935 275 3100

**Email**

helentb.5555@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh tobaee

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Unit3 , Garnet building, 38 mirza shirazi alley , Sanaye square .

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Phone**

+98 71 3233 0988

**Email**

helentb.5555@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh tobaee

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Unti3 , Garnet Buildingunti3 , 38 Mirzai Shirazi Alley ,  
Sanaye Square.

**City**

Shiraz

**Province**

Fars

**Postal code**

71967-36391

**Phone**

+98 71 3233 0988

**Email**

helentb.5555@gmail.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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Effectiveness of Dialectical Behavioral Therapy on

Perceived Stress of Ego and Cognitive Emotion

Regulation in Borderline Personality Disorder (BPD)

Patients (A case study of female patients aged 20 to 40  
referring to Ibn Sina Hospital in Shiraz)

**When the data will become available and for how long**

6 months after the results are published

**To whom data/document is available**

Working researchers

**Under which criteria data/document could be used**

There are no special conditions

**From where data/document is obtainable**

helentb.5555@gmail.com

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

by email

**Comments**