

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

efficacy Of Integration Of Biofeedback And Stand-Alone DBT Skills In Borderline Personality Disorder

Protocol summary

Study aim

Efficacy Of Integration Of Biofeedback And Stand-Alone DBT Skills In Borderline Personality Disorder

Design

two groups will be divided randomly in 2group. A case study with 4 subjects. baseline measured twice a week. . DBT combination therapy will be taught to the experimental group and DBT treatment to the control group. During the intervention and during 24 sessions, repeated assessments are performed in the same way for both groups once every two weeks. Measurements performed at the baseline stage are repeated at the end of treatment and one month after the end of treatment. It is worth noting that the experimental group will receive both treatments in all 12 sessions of intervention.

Settings and conduct

Interventions related to the control group will be performed in Asma Clinic belonging to the University of Social Welfare and Rehabilitation Sciences and the experimental group in the Brain and Cognition Clinic.

Participants/Inclusion and exclusion criteria

Minimum age 21 years ;main diagnosis of borderline personality disorder. At least a diploma Informed consent; Exit criteria: No psychotic disorders; No substance abuse; Do not take benzodiazepines; Failure to receive current psychological therapies; Intensification of active suicidal ideation; Existence of acute phase of bipolar disorder;

Intervention groups

intervention group will receive mindfulness and emotion regulation skills in addition to biofeedback control group solely will receive mindfulness and emotion regulation skills

Main outcome variables

Difficulty setting emotion Suicidal thoughts Depression Impulsive

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210421051033N1**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **retrospective**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

mohammad mahdi mehrabi tavana

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4417 8138

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mmh.mehrabitavana@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-06-26, 1400/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy Of Integration Of Biofeedback And Stand-Alone
DBT Skills In Borderline Personality Disorder

Public title

efficacy of psychotherapy in personality disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

personality disorder manifestation

Exclusion criteria:

Psychotic symptom Bipolar disorder Addiction

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: **4**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, people referred by a psychiatrist, and diagnosed with borderline personality disorder, are interviewed by the therapist and clinic staff. If the conditions of the fifth handbook of mental disorders based on personality disorder and the conditions for entering treatment are met, these people are randomly divided into two groups of intervention and control by random allocation software, each of group has a capacity of 2 people. The intervention group and the control group enter psychotherapy in two different centers

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 committtee of university of social welfare and rehabilitation science

Street address

NUMBER19,NESHAT2,MANOOCHERI,WESTERN
FERDOS

City

Tehran

Province

Tehran

Postal code

5467891234

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.USWR.REC.1399.251

Health conditions studied

1

Description of health condition studied

borderline personality disorder

ICD-10 code

F60.3

ICD-10 code description

Borderline personality disorder

Primary outcomes

1

Description

EMOTION regulation

Timepoint

four time two weekly

Method of measurement

emotion regulation ders

Secondary outcomes

1

Description

alexithymia

Timepoint

every 2 week

Method of measurement

toronto quastionare

Intervention groups

1

Description

Control group: Behavior therapy techniques 12 sessions. The first 6 sessions of mindfulness techniques based on the latest handbook of Dr. Marsha Linhan and the second 6 sessions of emotion regulation techniques based on the mentioned book. Each session lasts 45 minutes and two sessions per week. Equipment needed: treatment room with two chairs

Category

Treatment - Other

2

Description

Intervention group: Behavior therapy techniques plus alpha neurofeedback protocol 12 sessions. 6 introductory

sessions of mindfulness techniques based on Dr. Linhan's book for 30 minutes. And 15 minutes of mindfulness exercises with the help of pz point neurofeedback device. a8-12. Feedback is audio and the feedback process is blindfolded. Equipment: Neurofeedback device and conductive adhesive and alcohol for cleaning. The second 6 sessions of emotion regulation exercises according to Dr. Linhan's book for 45 minutes During the sessions, the skin conductance sensor will be used to give feedback to the patient on the activity of the autonomic system. Sodium chloride serum equipment for cleaning the index finger and skin conductance sensor.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Omid Rezayi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Personal-fund

Proportion provided by this source

100

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Mohammad Mahdi Mehrabi Tavana

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

information will be destroyed

When the data will become available and for how long

until dissertation submitted

To whom data/document is available

university department

Under which criteria data/document could be used

department check

From where data/document is obtainable

to researcher

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

requesting from department

Comments

Person responsible for updating data

Contact

Name of organization / entity

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Position

STUDENT

Latest degree

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