Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparing the effectiveness of Unified Protocol (UP) versus Dialectical Behavioral Therapy (DBT) in severity of borderline personality disorder and Post-traumatic stress disorder in individuals with both disorders

Protocol summary

Study aim
evaluate the effectiveness of unified protocol and dialectic behavior therapy among individuals with borderline personality disorder and Post-traumatic stress disorder i

Design
clinical trial among participants in two intervention groups and two blinded designs in which psychotherapists and assessors will be blind in 3 phases: baseline- -intervention and 36-month follow-ups. Participants will randomly assign to each treatment condition by using https://www.sealedenvelope

Settings and conduct
This study will be conducted at the clinical psychology office in Taleghani Hospital. Participants will be allocated randomly to two intervention groups. therapists, assessors, and data analyst will not be aware of the treatment conditions.

Participants/Inclusion and exclusion criteria
Inclusion:(1) met Diagnostic statistic mental disorder -5 diagnostic criteria for both borderline personality disorder and Post-traumatic stress disorder, and 2) were at least 18-years old. Excluded if they: 1) intellectual disability, 2) change in dosage and type of psychiatric medicine 3 months before the study, 3) met criteria for a psychotic disorder, bipolar disorder and brain diseases,4) required specialized treatment for high risk of suicide, 5) received 8 or more sessions of cognitive behavior therapy within last 5 years

Intervention groups
intervention group 1: The unified protocol consisted of a maximum of 36 sessions, 60-minute individual treatment sessions. intervention group 2: Dialectic behavior therapy maximum of 52 sessions that applied in individual and group skills training (1 hours/week)

Main outcome variables
severity of BPD and PTSD symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231106059970N2**
Registration date: **2024-12-07, 1403/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-07, 1403/09/17**
Update count: **0**

Registration date
2024-12-07, 1403/09/17

Registrant information

Name
Banafsheh Mohajerin

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparing the effectiveness of Unified Protocol (UP) versus Dialectical Behavioral Therapy (DBT) in severity of borderline personality disorder and Post-traumatic stress disorder in individuals with both disorders

Public title
evaluation of comparing the effectiveness of Unified Protocol and Dialectical Behavioral Therapy among individuals with borderline personality disorder and Post-traumatic stress disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Meet at least 5 out 9 Borderline personality disorder criteria of DSM-5-TR Meet Post-traumatic stress disorder criteria of DSM-5-TR at least 18 years old Be able to speak and read Farsi

Exclusion criteria:
intellectual disability change in dosage and type of psychiatric medicine 3-months prior to the study met criteria for a psychotic disorder, bipolar disorder, or organic mental disorder that assessed by SCID-5 (SCID-5) Required specialized treatment for high risk of suicide received 8 or more sessions of psychotherapies within last 5 years

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **68**
More than 1 sample in each individual
Number of samples in each individual: **34**
34

Randomization (investigator's opinion)
Randomized

Randomization description
G*Power software will be used for calculating sample size by indicating the margin of error of 0.05 and power of 0.95 total sample size will be 60. participants will be randomly allocated in two groups by using https://www.dcode.fr/random-selection and after that each group will receive one of the treatments randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
At first, all participants will receive information about both interventions and their effectiveness based on previous studies. After they sign an informed consent form, a master-level clinical psychologist (blind to the study hypotheses) will give a code to each participant to register them for this study. By using https://www.dcode.fr/random-selection, participants will be randomly allocated to each intervention group. Psychotherapists will not be aware of other treatment conditions, and assessors will assess participants by using the code. Only the researcher will know about each participant and their treatment conditions.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research ethics committees of Vice-chancellor in research Affairs- shahid Behehshti University of Me

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Arabi St.Yaman St. Velenjak.Tehran

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Approval date
2024-10-27, 1403/08/06

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.436

Health conditions studied

1

Description of health condition studied
Borderline personality disorder

ICD-10 code
F60.3

ICD-10 code description
Borderline personality disorder

2

Description of health condition studied
Post-traumatic Stress Disorder

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
borderline personality symptoms severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

using questionnaire Borderline symptoms checklist

2

Description

Post-traumatic stress symptoms severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using Post-traumatic stress disorder checklist questionnaire

Secondary outcomes

1

Description

anger severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using self-report the State–Trait Anger Expression Inventory–2 questionnaire

2

Description

dissociative symptoms severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using self-report the dissociative Experiences Scale questionnaire

3

Description

emotion dysregulation severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using the Difficulties in Emotion Regulation Scale questionnaire

4

Description

self-harm severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using self-report the deliberate Self-Harm Inventory questionnaire

5

Description

emptiness severity

Timepoint

before intervention start, after intervention, 6,12,18,24, and 36 months after intervention as a follow-up phase

Method of measurement

by using self-report the subjective Emptiness Scale questionnaire

Intervention groups

1

Description

Intervention group 1: The Unified Protocol (UP), is emotion-focused cognitive-behavioral therapy. It consists 5 core treatment modules: (1) mindful emotion awareness, (2) cognitive flexibility, (3) identifying and preventing patterns of emotion avoidance, (4) increasing awareness and tolerance of emotion-related physical sensations, and (5) interoceptive and situational emotion-focused exposures. Its 5 core modules are preceded by a module focused on enhancing motivation and an introductory module on the adaptive nature of emotions that provides a framework for understanding emotional experiences. Participants will receive at least 36 individual sessions weekly (1 hour).

Category

Treatment - Other

2

Description

Intervention group 2: Dialectical behavioral treatment (DBT) is a comprehensive cognitive behavioral therapy. DBT combines change-based interventions from behavior therapy (such as skills training, exposure, cognitive modification) with acceptance-based interventions. The first stage of treatment focuses on reducing high-risk behaviors and increasing behavioral skills in emotion regulation, distress tolerance, interpersonal effectiveness, and mindfulness. Post-traumatic stress disorder is targeted as needed in the second stage of treatment. Standard DBT is typically delivered at least 52 sessions of outpatient treatment consisting of four modes: (i) individual therapy (1 hour/week), (ii) group skills training (2.5 hours/week), (iii) therapist consultation team (1 hour/week), and (iv) between-session telephone consultation (as needed)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Data and analysis will be available at a reasonable request.

When the data will become available and for how long

after Publication data will be available

To whom data/document is available

Data will be available for psychologists and psychiatrists

Under which criteria data/document could be used

upon reasonable request

From where data/document is obtainable

Data will be available after the publication of the results upon reasonable request by sending an email to the corresponding author

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

Data will be available after the publication of the results upon reasonable request by sending an email to the corresponding author

Comments