Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Dialectical Behavior Therapy for Posttraumatic Stress Disorder (DBT-PTSD) for Treatment Outcome of Non-Suicidal Self-Injury Disorder in People with a history of Childhood Abuse and Determining the Mechanisms of Change

Protocol summary

Study aim
Determining the effectiveness of dialectical behavior therapy for post-traumatic stress disorder in the treatment outcome of non-suicidal self-injury in individuals with childhood maltreatment

Design
A randomized controlled clinical trial, consisting of 30 subjects randomly divided between two groups. A chance box is used for selection.

Settings and conduct
Research proposal: The required sample of adolescents referred to the Iranian Psychiatric Hospital is collected by convenience sampling and randomly assigned to the experimental and control groups. First, a pre-test is taken from the groups, then 12 psychotherapy sessions are administered to the two groups separately. At the end of the sessions (posttest) and after 3 months, follow-up on the research variables is performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Diagnosis of non-suicidal self-injury disorder b 2- Experience of childhood maltreatment 3- Age range between 16 and 24 years 4- Education at least sixth grade Exclusion criteria: 1- Receiving other psychological treatments in the past six months 2- Presence of psychotic symptoms based on SCID 3- Presence of organic diseases and severe physical diseases 4- Substance use disorder and bipolar disorder types I and II 5-Severe personality disorders

Intervention groups
The experimental group will receive 12 weeks of dialectical behavior therapy for posttraumatic stress disorder (DBT-PTSD).The control group will receive 12 sessions of trauma-focused cognitive behavioral therapy.

Main outcome variables
Non-suicidal self-harm symptoms; negative cognitions; perceived emotional invalidation; depressive symptoms; emotion regulation symptoms; generalized anxiety symptoms and occupational-social adjustment

General information

Reason for update

Acronym
DBT-PTSD & NSSI

IRCT registration information
IRCT registration number: **IRCT20250117064414N1**
Registration date: **2025-02-12, 1403/11/24**
Registration timing: **prospective**

Last update: **2025-02-12, 1403/11/24**
Update count: **0**

Registration date
2025-02-12, 1403/11/24

Registrant information

Name
Younes Zaheri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-04, 1404/01/15

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Dialectical Behavior Therapy for Posttraumatic Stress Disorder (DBT-PTSD) for Treatment Outcome of Non-Suicidal Self-Injury Disorder in People with a history of Childhood Abuse and Determining the Mechanisms of Change

Public title
Effectiveness of Dialectical Behavior Therapy for Posttraumatic Stress Disorder (DBT-PTSD) for Treatment Outcome of Non-Suicidal Self-Injury Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of non-suicidal self-harm disorder based on the Structured Clinical Interview for DSM-5 (SCID-I) as the primary diagnosis and comorbidity Experience of childhood maltreatment (must be one of the maltreatment cases, physical or sexual abuse). Age range between 16 and 24 years Education at least sixth grade of primary school
Exclusion criteria:
Receiving other psychological treatments in the past six months Presence of psychotic symptoms based on SCID Presence of organic diseases and severe physical diseases such as multiple sclerosis (MS) based on the patient's record Substance use disorder and bipolar disorder type 1 and 2 Serious difficulty in understanding questionnaire items Severe personality disorders
Age
From **16 years** old to **24 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
30 people with Non-Suicidal Self-Injury Disorder will be categorized into 2 groups (control, experiment) randomly. the names of all subjects will be written separately on piece of papers.Then they are thrown into a box and members of both control and experiment groups are selected randomly . The control and experiment groups each included 15 members.
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
Research Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences (IUMS),Next to Milad Tower, Shahid Hemmat Highway, Tehran, IRAN
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Postal code
1449614535
Approval date
2024-04-27, 1403/02/08
Ethics committee reference number
IR.IUMS.REC.1403.069

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Non-Suicidal Self-Injury symptoms
Timepoint
Non-Suicidal Self-Injury symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment course.
Method of measurement
Sanson et al. Self-harm Questionnaire

2

Description
Negative cognition symptoms
Timepoint
Negative cognition symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment

course.

Method of measurement

Posttraumatic Cognitions Inventory

3

Description

Perceived Invalidation of Emotion symptoms

Timepoint

Perceived Invalidation of Emotion symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment course.

Method of measurement

The Perceived Invalidation of Emotion Scale

4

Description

Depression symptoms

Timepoint

Depression symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment course.

Method of measurement

Beck Depression Inventory-II

5

Description

Emotion regulation symptoms

Timepoint

Emotion regulation symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment course.

Method of measurement

Emotion Regulation Questionnaire-8

6

Description

Generalized anxiety symptoms

Timepoint

Generalized anxiety symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, three months after the last session of the treatment course.

Method of measurement

Generalized Anxiety Disorder Questionnaire-7

Secondary outcomes

1

Description

The Work and Social Adjustment Scores

Timepoint

The Work and Social Adjustment Scores are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, a month after the last session of the treatment course.

Method of measurement

The Work and Social Adjustment Scale

Intervention groups

1

Description

Intervention group: 12 weeks of dialectical behavior therapy for post-traumatic stress disorder will be performed in the form of group (90 minutes) and individual (45 minutes) weekly sessions that include dialectical behavior therapy techniques. The treatment steps include: 1- Behavioral analysis, specific dialectical behavior therapy skills for behavior control (identifying the individual's strategies for escaping from initial trauma-related emotions (such as dissociation/dissociation, non-suicidal self-harm) and controlling behavior), 2- Cognitive and exposure-based interventions focused on the trauma, coping skills (balancing memory activation and awareness of being present in the present and reducing dissociative/dissociative features), and 3- Fundamental acceptance of the facts related to the trauma (returning to normal daily life).

Category

Behavior

2

Description

Control group: trauma focused - cognitive behavioral therapy (one 45-minute session per week for each individual)will be performed for the control group over 12 weeks. The treatment phases include: 1- consolidation and skill building, parent guidance and feedback to parents, coping skills training (focusing on therapeutic participation and psychoeducation about the prevalence, impact, and treatment of the trauma/incident, strengthening parental support for the patient, employing coping skills), 2- narrative (retelling) and processing of the trauma/incident, focusing directly on the details of traumatic memories, challenging maladaptive beliefs, meaning, and consequences of the trauma/incident (processing difficult feelings and supporting these feelings, sharing the patient's narrative of the trauma/incident with the parents to gain support), and 3- integration and consolidation, joint parent-patient meetings, sharing the narrative, and teaching safety skills (preventing revictimization).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Psychiatric Cente

Full name of responsible person
Fahimeh Fathali Lavasani

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Sponsors / Funding sources

1

Sponsor

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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?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Younes Zaheri

Position
Ph.D student

Latest degree
Ph.D.

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
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
Yes - There is a plan to make this available
Title and more details about the data/document
The outcome and conclusion of the data will be published in article after the end of the interventions. All questionnaires and scales that are used, are available.
When the data will become available and for how long
The beginning of availability period will be winter of 1404
To whom data/document is available
Will be available for everyone.
Under which criteria data/document could be used
no analysis on data is allowed. Only the protocol can be used and referenced.
From where data/document is obtainable
Younes Zaheri\ zzaheriyones@gmail.com
What processes are involved for a request to access data/document
After requesting an email, it will be sent within a maximum of two weeks.
Comments