Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of dialectical behavior therapy with unified transdiagnostic therapy on the psychological consequences and emotional eating of patients with emotional disorders and determining the mechanisms of change

Protocol summary

Study aim

The aim of the study is to compare the effectiveness of dialectical behavior therapy with integrated trans-diagnostic therapy on the psychological outcomes and emotional eating of patients with emotional disorders and to analyze the patients' experience of the treatment and the facilitating and inhibiting factors affecting the outcome of the treatment

Design

A controlled, parallel-group, single-blind, randomized, sealed-envelope clinical trial on 26 patients

Settings and conduct

Psychiatry and psychotherapy clinics and clinics or obesity clinics in Tehran

Participants/Inclusion and exclusion criteria

Age range from 18 to 65 years, diagnosis of emotional disorders (depressive disorders-anxiety disorders-obsessive/compulsive disorders based on a structured clinical interview), having emotional eating based on the interview and the score obtained from the emotional eating questionnaire (patient scores) In the emotional eating scale, one standard deviation is higher than the mean (M = 52.62, SD = 18.81), age between 18 and 65 years, having at least a high school diploma

Intervention groups

In the experimental group, 12 sessions of integrated transdiagnostic therapy are performed, and in the control group, 12 sessions of dialectical behavior therapy are performed.

Main outcome variables

Emotion regulation, anxiety intensity, depression intensity, affect control, mindfulness, body mass index, distress tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240705062334N1**
Registration date: **2024-08-01, 1403/05/11**
Registration timing: **prospective**

Last update: **2024-08-01, 1403/05/11**
Update count: **0**

Registration date

2024-08-01, 1403/05/11

Registrant information

Name

Mitra Borji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

mitra.borji@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

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
Comparing the effectiveness of dialectical behavior therapy with unified transdiagnostic therapy on the psychological consequences and emotional eating of patients with emotional disorders and determining the mechanisms of change

Public title
Effect of psychological therapy on emotional eating

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of emotional disorders Having emotional eating Literacy of at least a diploma

Exclusion criteria:
Suffering from manic states or having psychotic symptoms based on structured clinical interview Having an eating disorder based on a structured clinical interview Having a substance use disorder based on a structured clinical interview There is a level of suicide risk

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Person with emotional disorder and emotional eating are selected using simple randomization method. The randomization unit is Individual. Through a random table of numbers, which are randomly generated without any pattern or order, the names of the participants will be collected as a set of numbers and the numbers will be used to categorize different groups. Odd numbers are placed in the intervention group and odd numbers in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
First, we create random sequences using web-based randomization.Then, based on the size of the research sample, we prepare a number of envelopes and record each random sequence created on a card, and place the cards in envelopes in order and put them in a box.And according to the order of entry of qualified subjects, we open one of the envelopes and the case group is revealed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Jalal Al Ahmad St., South Amirkabir, South Shayk

City
Tehran

Province
Tehran

Postal code
1461614745

Approval date
2024-06-02, 1403/03/13

Ethics committee reference number
IR.IUMS.REC.1403.207

Health conditions studied

1

Description of health condition studied
Emotional Disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
emotional eating

Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study

Method of measurement
Emotional Eating Scale

2

Description
Anxiety intensity

Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study

Method of measurement
Beck Anxiety Questionnaire

3

Description
Depression intensity

Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Beck Depression Questionnaire

4

Description
Distress Tolerance
Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Distress Tolerance Scale

5

Description
Mindfulness
Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Southampton mindfulness questionnaire

6

Description
Emotion Regulation
Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Emotion regulation difficulty questionnaire

7

Description
Affective control
Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Affective control scale

8

Description
Body Mass Index
Timepoint
At the beginning of the study, at the end of the study, 3 months after the end of the study
Method of measurement
Dividing weight (kilograms) by height (meters) to the power of 2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 12 one-hour sessions of individual therapy will be conducted with the integrated Trans-diagnostic treatment method
Category
Treatment - Other

2

Description
Control group: Control group: 12 one-hour sessions of individual therapy with dialectical behavior therapy will be done
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized and subspecialized psychiatry and clinical psychology clinic
Full name of responsible person
Mina mohsennia
Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences
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Tehran
Province
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Postal code
1449614535
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Hemat Highway, next to Milad Tower, Iran University of Medical Sciences, 5th floor of the central headquarters
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1449614535

Phone
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info@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Mitra Borji

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available