Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of unified transdiagnostic treatment on emotional, cognitive, and neuropsychological symptoms and indicators in individuals with body dysmorphic disorder comorbid with emotional disorders: A clinical trial study

Protocol summary

Study aim

The present study aims to investigate the effectiveness of unified transdiagnostic treatment on emotional, cognitive, and neuropsychological symptoms and indicators in individuals with body dysmorphic disorder (BDD) comorbid with emotional disorders in a clinical trial study.

Design

34 participants suffering from BDD with comorbid emotional disorders will be randomized (using the Permuted block randomization method) and blinded in both treatment and control groups.

Settings and conduct

Allocation of participants will be administered by someone other than a therapist. For the allocation of the participants, a Permuted block randomization method will be used. Referrals for the treatment and wait-list groups will be from the counseling center of the University of Kurdistan and mental health professionals.

Participants/Inclusion and exclusion criteria

The study population will include people with body dysmorphic disorder (BDD) and comorbid emotional disorders in Sanandaj in 2023-2024. The sample of research also will include some people with BDD with comorbid emotional disorders.

Intervention groups

The individuals suffering from body dysmorphic disorder (BDD) with comorbid emotional disorders will randomly be assigned to two groups including UP and wait-list.

Main outcome variables

Body dysmorphic disorder; depression and Anxiety; difficulties in emotion regulation; anxiety sensitivity; cognitive emotion regulation; cognitive fusion; cognitive avoidance; inhibition; working memory; Problem-solving.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231001059577N1**
Registration date: **2024-01-18, 1402/10/28**
Registration timing: **prospective**

Last update: **2024-01-18, 1402/10/28**
Update count: **0**

Registration date

2024-01-18, 1402/10/28

Registrant information

Name
Fateme Etaati
Name of organization / entity
The University of Kurdistan
Country
Iran (Islamic Republic of)
Phone
+98 21 5591 5918
Email address
fateme.etaati@uok.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-25, 1402/11/05

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of unified transdiagnostic treatment on emotional, cognitive, and neuropsychological symptoms and indicators in individuals with body dysmorphic disorder comorbid with emotional disorders: A clinical trial study

Public title
The effectiveness of unified transdiagnostic treatment on body dysmorphic disorder comorbid with emotional disorders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of BDD disorder according to DSM-5 Having a minimum score of 53 in the body image concern inventory of Littleton et al The presence of at least one emotional disorder Age range of people from 18 to 45 years Willing to participate in the study by signing a written consent form The ability to speak Persian in all assessments Not having serious mental disorders such as psychosis, bipolar type I or II Not having suicidal thoughts No abuse of benzodiazepines, antipsychotics, and SSRI medicines in the last 6 months

Exclusion criteria:
Need for medical intervention Receiving psychotherapy sessions at the same time Concerns about weight-related eating disorders Unwillingness to continue participating at any time in the study Absence of more than 3 sessions in treatment sessions

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
After the people with body dysmorphic disorder comorbid with emotional disorders were selected based on the inclusion and exclusion criteria, they will be allocated to two equal groups of treatment and control using the blocking randomization method. The coin toss method will be used to allocate people in each of the groups (Treatment and control). The blocking method will be used to balance the number of samples assigned to each of the study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, a clinical interview will be conducted by a clinical expert therapist to evaluate the inclusion and exclusion criteria. After obtaining informed consent to participate in the research, the participants will be randomly assigned to groups (treatment and control groups), in such a way that the participants have no knowledge of which group (treatment group or control group) they will be placed in. will not have Allocating participants in groups and taking the tests of this research in all three stages (Pre-treatment; post-treatment; follow-up) will be done by someone other than the therapist.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee in biomedical research

Street address
Pasdaran Blvd., University of Kurdistan., Central organization

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Approval date
2023-12-23, 1402/10/02

Ethics committee reference number
IR.UOK.REC.1402.015

Health conditions studied

1

Description of health condition studied
body dysmorphic disorder comorbid with emotional disorders

ICD-10 code
F45.22

ICD-10 code description
Body dysmorphic disorder

Primary outcomes

1

Description
Score of Body Image Concern from BICI questionnaire

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

Body Image Concern Inventory

2

Description

Score of depression and Anxiety from DASS-21 questionnaire

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

DASS-21 questionnaire

Secondary outcomes

1

Description

Score of cognitive fusion from CFQ

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

CFQ questionnaire

2

Description

Score of cognitive emotion regulation from CERQ

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

CERQ questionnaire

3

Description

Score of cognitive avoidance from CAQ

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

CAQ questionnaire

4

Description

Score of difficulties in emotion regulation from DERS

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

DERS questionnare

5

Description

Score of anxiety sensitivity from ASI

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

ASI questionnaire

6

Description

Score of Problem-solving from Tower of London

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

Tower of London software

7

Description

Score of inhibition from go/no go test

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

Go/no go software

8

Description

Score of working memory from n-back test

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

N- back software

Intervention groups

1

Description

Intervention group: group 1: UP group. Unified protocol for transdiagnostic of emotional disorders consists of a maximum of 10, 45-minute individual treatment sessions. The UP targets and regulates emotional experiences by increasing emotion awareness and cognitive flexibility; identifying emotion-driven behaviors (EDBs) and replacing them with adaptive behaviors; identifying and preventing patterns of emotion avoidance; increasing awareness and confronting physical sensations, and facing emotions in situations. The treatment is preceded by enhancing the motivation and readiness of individuals for change and treatment engagement. Finally, the treatment ends by considering the progress of treatment and developing relapse prevention strategies.

Category

Treatment - Other

2

Description

Control group: wait-list group for Unified protocol. After completion of follow-up sessions of intervention groups, the UP treatment will be applied as intervention group 1.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Counselling center of University of Kurdistan

Full name of responsible person
Mehdi Zemestani

Street address
Pasdaran Blvd; University of Kurdistan

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Phone
+98 87 3366 6746

Fax

Email
m.zemestan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Kurdistan

Full name of responsible person
Ali Akbar Mozafari

Street address
Pasdarsn Blvd; University of Kurdistan

City
Sanandaj

Province
Kurdistan

Postal code
info@uok.ac.ir

Phone
+98 87 3362 7722

Fax

Email
a.mozafari@uok.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
University of Kurdistan

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
University of Kurdistan

Full name of responsible person
Fateme Etaati

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Pasdaran Blvd; University of Kurdistan

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Phone
087-33664600-8

Fax
+98 21 6600 0021

Email
fateme.etaati@uok.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Kurdistan

Full name of responsible person
Farzad Nasiri

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Pasdaran Blvd; University of Kurdistan

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Phone
087-33664601-2246

Email
nasiri.uok@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Kurdistan

Full name of responsible person
Fateme Etaati

Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Pasdaran Blvd; University of Kurdistan
City
Sanandaj
Province
Kurdistan
Postal code
66177-15175
Phone
087-33664600-8
Email
fateme.etaati@uok.ac.ir

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
Part of the data including information about the main consequence can be shared.
When the data will become available and for how long
Start of accessibility will be one year after printing the results.
To whom data/document is available
Data will only be available to researchers working in academic institutions.
Under which criteria data/document could be used
Requests for data are only permitted for intercultural studies or the studies of meta-analysis.
From where data/document is obtainable
Researchers can use the mentioned communication channel to receive the desired documents or data. Email: nasiri.uok@yahoo.com
What processes are involved for a request to access data/document
Data will be provided by email or post after evaluation of the request.
Comments