

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Efficacy of Transdiagnostic therapy on psychological variables and reduce symptoms in Adolescents with sub-clinical symptoms of body dysmorphic disorder

Protocol summary

Study aim

Effectiveness of transdiagnostic cognitive-behavioral therapy in cognitive, social, emotional variables and reducing symptoms in adolescents with preclinical symptoms of body deformity disorder

Design

The clinical trial, with a waiting list group, is one-sided blind and a sample size of 62 people will be selected and they will be placed in two intervention and waiting list groups based on the assignment of random blocks. Triple evaluations will be done by one of the research colleagues, and the therapist will not participate in the data analysis.

Settings and conduct

Sampling, evaluation and treatment will be done in Beheshti Hospital. The samples will be placed in two intervention and waiting list groups based on random block assignment. Therapists and participants will be blinded to group allocation and assessment information.

Participants/Inclusion and exclusion criteria

Inclusion Having symptoms of body deformity disorder at the preclinical level Age range between 12-18 years Interest of the participants to participate in the research Exclusion Having severe psychiatric disorders Drug and alcohol consumption in the last three months Receiving cognitive-behavioral interventions receiving drug therapy within a month before starting the intervention Having a chronic medical disease Receiving another similar psychological intervention

Intervention groups

The intervention group will receive UP extradiagnostic treatment. This protocol has 8 modalities that focus on cognitive restructuring, exposure to physical symptoms, exposure and response inhibition, and emotion regulation. The number of sessions is 12-18 sessions.

Main outcome variables

Social adjustment Physical deformity Inconsistent self-

focused attention depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210428051113N2**

Registration date: **2023-03-16, 1401/12/25**

Registration timing: **prospective**

Last update: **2023-03-16, 1401/12/25**

Update count: **0**

Registration date

2023-03-16, 1401/12/25

Registrant information

Name

vahideh javadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3372 5349

Email address

vjavadi76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Transdiagnostic therapy on psychological variables and reduce symptoms in Adolescents with sub-clinical symptoms of body dysmorphic disorder

Public title

Efficacy of Transdiagnostic therapy in Adolescents with sub-clinical symptoms of body dysmorphic disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having symptoms of body dysmorphic disorder at the preclinical level Age range between 12-18 years Interest of the participants to participate in the research based on written consent

Exclusion criteria:

Having severe psychiatric disorders (psychotic spectrum, bipolar disorder) Drug and alcohol consumption in the last three months Receiving cognitive-behavioral interventions in the last 5 years receiving drug therapy within a month before starting the intervention Having a chronic medical disease Receiving another similar psychological intervention at the same time as the current research

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to have an equal number of participants in the intervention and control groups at consecutive but equal time intervals, two blocks will be considered and the samples will be placed in the two intervention groups and the waiting list based on the assignment of random blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done in connection with the therapist regarding the allocation of people in the treatment groups and waiting list, as well as evaluation and evaluation information of three stages.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

Street address

Arg gate, Shahid Beheshti Hospital

City

Zanjan

Province

Zanjan

Postal code

4514147814

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

IR.ZUMS.REC.1401.312

Health conditions studied**1****Description of health condition studied**

body dysmorphic disorder

ICD-10 code

F45.2

ICD-10 code description

Hypochondriacal disorders

Primary outcomes**1****Description**

social adjustment

Timepoint

before the intervention, after the intervention and three months after the intervention

Method of measurement

The score a person gets from Bell's social adjustment test.

2**Description**

body dysmorphic

Timepoint

before the intervention, after the intervention and three months after the intervention

Method of measurement

The score a person gets in the body deformity concern questionnaire (DCQ).

3

Description

Negative self-focused attention

Timepoint

before the intervention, after the intervention and three months after the intervention

Method of measurement

The score that a person gets in the focus of attention questionnaire (FAQ).

4

Description

Depression

Timepoint

before the intervention, after the intervention and three months after the intervention

Method of measurement

The score that a person gets from the Hamilton questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive integrated metadiagnostic treatment. This treatment has 8 modalities and is performed in 8-12 sessions. The duration of each session is 45 minutes. The content of therapeutic modalities includes emotional awareness, cognitive restructuring, exposure to physical symptoms, exposure and inhibition of response, and parental modality, which focuses on teaching maladaptive educational behaviors and their alternatives. And protocol training forms and worksheets are also given to clients at the end of the sessions.

Category

Treatment - Other

2

Description

Control group: A waiting list group that does not receive extradiagnostic treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Seyedeh Elnaz Mousavi

Street address

Gate of Beheshti Hospital citadel

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Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mahdi Babamoradi

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Karmandan ,Mahdavi Street, Zanjan University of Medical Sciences

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Seyedeh Elnaz Mousavi

Position

Faculty of Zanjan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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psychologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To maintain the confidentiality of client information

Study Protocol

Yes - There is 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

Undecided - It is not yet known if there will be 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

Title and more details about the data/document

The information obtained from the evaluations and the results of the questionnaire and interview tools will be used for data analysis.

When the data will become available and for how long

7 months after the publication of the results

To whom data/document is available

Health researchers in academic and scientific institutions

Under which criteria data/document could be used

Information will be provided to researchers under conditions of confidentiality and in order to advance research in the field of meta-diagnostic treatment and complete the history of this treatment.

From where data/document is obtainable

Correspond author and colleagues of this research

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

Communicating with the responsible author and requesting permission in writing and having permission to receive data for access

Comments