

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Designing and developing a treatment model to prevent body deformity in women

Protocol summary

Study aim

Designing and developing a treatment model to reduce body deformity disorder in women

Design

Clinical trial without control group, on 3 patients

Settings and conduct

In this research, A-B-A design was used along with a multiple baseline, carried out at Ferdowsi University of Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being women; Body dysmorphic disorder; Age between 20 and 50 years old. Non-inclusion criteria: Intellectual disability

Intervention groups

The therapy is a combination of ACT techniques, schema therapy, and mindfulness. The intervention is arranged and presented in 16 sessions: 1. Preparation for starting the treatment 2. Preparation of the treatment context to pass from the mechanical state to conscious 3. Preparing the treatment context for acceptance 4. Constructive despair - creating a space for new solutions 5. Attention to awareness, acceptance, goals and values

Main outcome variables

Body Dysmorphic Disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220730055583N1**

Registration date: **2023-02-09, 1401/11/20**

Registration timing: **retrospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **0**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

ali azamrajabian

Name of organization / entity

Ferdowsi university of mashhad

Country

Iran (Islamic Republic of)

Phone

+98 915 797 0967

Email address

ali.azamrajabian@mail.um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and developing a treatment model to prevent body deformity in women

Public title

The effect of combined treatment to reduce body dysmorphic disorder in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being women Body dysmorphic disorder Age between 20 and 50 years old

Exclusion criteria:

Intellectual disability

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **3**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ferdowsi University of Mashhad

Street address

Ferdowsi University of Mashhad; Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

91177948974

Approval date

2022-08-21, 1401/05/30

Ethics committee reference number

IR.UM.REC.1401.105

Health conditions studied

1

Description of health condition studied

Body dysmorphic disorder

ICD-10 code

F45.22

ICD-10 code description

Body dysmorphic disorder

Primary outcomes

1

Description

Body deformity disorder

Timepoint

At the beginning of the study and 3, 6, 9, 13 and 16 weeks after the start of the treatment

Method of measurement

content analysis

Secondary outcomes

empty

Intervention groups

1

Description

The therapy is a combination of ACT techniques, schema therapy, and mindfulness. The intervention is arranged and presented in 16 sessions: 1.Preparation for starting the treatment 2. Preparation of the treatment context to pass from the mechanical state to conscious3. Preparing the treatment context for acceptance 4. Constructive despair - creating a space for new solutions 5. Attention to awareness, acceptance, goals and values

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ferdowsi University of Mashhad

Full name of responsible person

Mohammad Javad Asghari ebrahimabad

Street address

Ferdowsi University of Mashhad; Azadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research and Technology of Ferdowsi University of Mashhad Ferdowsi

Full name of responsible person

Reza Lotfi

Street address

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91177941974

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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

Vice President of Research and Technology of Ferdowsi University of Mashhad Ferdowsi

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**

Ferdowsi University of Mashhad

Full name of responsible person

Ali Azam Rajabian

Position

STUDENT

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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Fax**Email**

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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

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

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts from 2023

To whom data/document is available

People who are also engaged in the industry can apply to receive them.

Under which criteria data/document could be used

For practical use

From where data/document is obtainable

ail.azamrajabian@mail.um.ac.ir علی اعظم رجیبیان

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

The treatment is being implemented and after the final evaluation of the initial questionnaires that were collected from the patients in December 1401, the post-test results will be obtained by May 30.

Comments