Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 conscious3. 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)
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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
۹۱۷۷۹۴۸۹۷۴
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
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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

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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
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Person responsible for updating data

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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 رجبیان

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