Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Compassion-Based Therapy (CFT) on Internalized Shame and Social Anxiety in Female Students with Body Dysmorphic Disorder in Azad University

Protocol summary

Study aim

The Effectiveness of Compassion-Based Therapy (CFT) on Internalized Shame and Social Anxiety in Female Students with Body Dysmorphic Disorder in Azad University

Design

A controlled clinical trial with parallel groups, without blinding, randomized, on 30 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

The statistical population of the present study includes all female students at various levels of education at Islamic Azad University, Ahvaz Branch, in the second semester of the academic year 1404-1405 who have body dysmorphic syndrome. In the sample selection stage, the available sampling method is used. After selecting the samples to a volume of 30 people based on the research entry and exit criteria, the participants will be randomly assigned to two groups: "Compassion-based couple therapy" (intervention group) and "waiting list" (control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Score above the cut-off point on the Body Dysmorphic Disorder Questionnaire, girls aged 18 to 30, being a student at Ahvaz Azad University.
Exclusion criteria: Unwillingness to participate in the study, receiving psychological services or medication

Intervention groups

Intervention group 1: All individuals who will receive compassion-based therapy. Control group: All individuals who will not receive any intervention.

Main outcome variables

Internalized Shame, Social Anxiety, Body Dysmorphic Disorder Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260510069338N1**
Registration date: **2026-05-14, 1405/02/24**
Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**
Update count: **0**

Registration date

2026-05-14, 1405/02/24

Registrant information

Name
Atefeh Shomalzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3333 3333
Email address
atefehshomalzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-26, 1405/03/05

Expected recruitment end date

2026-06-10, 1405/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effectiveness of Compassion-Based Therapy (CFT) on Internalized Shame and Social Anxiety in Female Students with Body Dysmorphic Disorder in Azad University

Public title
Investigating the effectiveness of compassion-based therapy on internalized shame and social anxiety in female students

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Score above the cut-off point on the Body Dysmorphic Disorder Questionnaire Girls aged 18 to 30 Being a student at Ahvaz Azad University.

Exclusion criteria:

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The statistical population of the present study consists of all female students at different educational levels of Islamic Azad University, in the second semester of the 2025–2026 academic year who exhibit body dysmorphic symptoms. In this type of effectiveness study, a two-stage approach is typically used: in the sample selection stage, convenience sampling is employed. After selecting the sample to a size of 30 participants based on the study's inclusion and exclusion criteria, the participants will be randomly assigned to two groups: Compassion-Based Couple Therapy (intervention group) and waiting list (control group). Randomization will be carried out using variable block randomization with block sizes of 4 and 6 by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Microsoft Excel and then placed in opaque, sealed, and numbered envelopes so that neither the researcher nor the participants will be aware of the allocation sequence (allocation concealment). The envelopes will be opened, and the assigned group will be revealed only at the time each participant enters the study. To ensure the equality of baseline variables, such as anxiety level and age, their distribution across the two groups will be examined during the statistical analysis phase.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of Ahvaz Branch

Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Approval date
2026-04-11, 1405/01/22

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.024

Health conditions studied

1

Description of health condition studied
Body Dysmorphic Disorder Syndrome

ICD-10 code
F45.22

ICD-10 code description
Body Dysmorphic Disorder

Primary outcomes

1

Description
Internalized Shame

Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement
The measurement method was David R. Cook's (1987) Internalized Shame Scale.

2

Description
Social Anxiety

Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement
The measurement method will be the SPIN questionnaire by Kathleen Connor et al. (2000).

3

Description
Body dysmorphic disorder syndrome
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
The measurement method will be the revised Yale-Brown Obsessive-Compulsive Scale for Body Dysmorphic Disorder by Katherine Phillips et al. (1997).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Compassion-Focused Therapy. Session Duration: 60 minutes.Total Sessions: 8 sessions. Session Frequency: Twice per week.Therapeutic Tools Used.This intervention focuses on activating internal compassion resources and reducing self-criticism, incorporating guided therapeutic dialogue, mindfulness exercises, self-compassion imagery, soothing breathing techniques, and compassionate writing exercises.Summary of Session Content: Session 1: Introduction to the therapy, explanation of compassion and shame concepts, pre-test administration. Session 2: Identification of thoughts and behaviors associated with internalized shame and social anxiety. Session 3: Training in compassionate imagery and soothing breathing techniques. Session 4: Mindfulness practice and non-judgmental acceptance of emotions. Session 5: Compassionate letter writing and strengthening self-compassion. Session 6: Examination of factors contributing to self-criticism and shame. Session 7: Training in coping strategies and relaxation techniques. Session 8: Conclusion, review of learned material, post-test administration, and scheduling of follow-up assessment.
Category
Treatment - Other

2

Description
Control group: The control group will not receive any intervention during the research, but will receive the intervention after data collection to prevent factors that threaten the internal validity of the research, such as compensatory competition from the control group or demoralization.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Ahvaz Branch
Full name of responsible person
Atefeh Shomalzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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a_eigder@ymail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University

Full name of responsible person
Atefeh Shomalzadeh

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable