Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of compassion therapy based on mindfulness on reducing emotional failure symptoms and social adjustment of female students to love failure at Iranshahr University of Medical Sciences in 2024-2025

Protocol summary

Study aim
To evaluate the effectiveness of compassion-focused therapy based on mindfulness in reducing emotional failure symptoms and improving social adjustment among female students

Design
Randomized clinical trial with control group, parallel design, phase 2 on 30 students. Randomization was done using a random number table.

Settings and conduct
The study was conducted at Iranshahr University of Medical Sciences. Participants were randomly assigned after screening. Therapy sessions were held in-person and in groups. No blinding was performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: female student, age 18 to 30, romantic breakup within the past six months, written informed consent, no concurrent psychological treatment, no severe psychiatric disorder Exclusion criteria: use of psychoactive drugs, unwillingness to attend therapy sessions, age outside the defined range, not enrolled at Iranshahr University of Medical Sciences

Intervention groups
Intervention Group: Participants in this group attend eight weekly in-person sessions of compassion-focused therapy based on mindfulness. The sessions include mindfulness exercises, self-compassion training, emotional acceptance, and reduction of rumination. Control Group: Participants in this group do not receive any psychological intervention and only take part in the pre-test and post-test assessments.

Main outcome variables
Emotional failure symptoms; social adjustment; score on emotional failure questionnaire; score on social adjustment questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250825066985N1**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-01, 1404/06/10**
Update count: **0**

Registration date
2025-09-01, 1404/06/10

Registrant information

Name
Fatemeh Firouzi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-19, 1404/05/28

Expected recruitment end date
2025-09-19, 1404/06/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of compassion therapy based on mindfulness on reducing emotional failure symptoms and social adjustment of female students to love failure at Iranshahr University of Medical Sciences in 2024-2025

Public title
Effectiveness of compassion therapy based on mindfulness on reducing emotional failure symptoms and social adjustment of female students to love failure

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Absence of severe psychiatric or psychological disorders Ability to attend therapy sessions regularly High score on the emotional failure questionnaire Written informed consent to participate in the study Age between 18 and 30 years

Exclusion criteria:
No experience of romantic breakup Age below 18 or above 30 years Not being a student at Iranshahr University of Medical Sciences being male

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
1. Randomization Method: Simple randomization was used. Participants were randomly assigned to either the intervention or control group. 2. Unit of Randomization: Individual; each participant was independently allocated to one of the two groups. 3. Stratified Randomization: No stratified randomization was applied in this study. 4. Randomization Tool: A random number table was used to perform the allocation. 5. Sequence Generation: The allocation sequence was generated by the second researcher using a random number table and stored as a coded list. 6. Allocation Concealment: Due to the nature of group-based psychotherapy, allocation concealment for participants and therapists was not feasible. However, the statistical analyst was blinded to group assignments.

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 the Faculty of Medical Sciences, Islamic Azad University, Zahedan Branch

Street address
Sistan and Baluchestan _ Iranshahr County _ Shahr Daraz, end of Moallem Street, K:24

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
۹۹۱۸۶۴۵۸۵۴

Approval date
2025-08-18, 1404/05/27

Ethics committee reference number
IR.IAU.ZAH.REC.1404.062

Health conditions studied

1

Description of health condition studied
Effectiveness of compassion therapy based on mindfulness on reducing emotional failure symptoms and social adjustment of female students to love failure at University of Medical Sciences

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Score on the emotional failure questionnaire before and after the intervention

Timepoint
Measured at baseline (before the intervention) and after completion of therapy sessions (week 8)

Method of measurement
Emotional failure was measured using the Love Trauma Symptom Inventory developed by Ross in 1999. This instrument includes 10 items that assess physical, emotional, cognitive, and behavioral distress. Scoring is based on a five-point scale, and a score of 20 is considered the cutoff point.

2

Description
Score on the social adjustment questionnaire before and after the intervention

Timepoint

Measured at baseline (before the intervention) and after completion of therapy sessions (week 8)

Method of measurement

Social adjustment was measured using the Social Adjustment Questionnaire developed by Sohrabi and Samani in 2011. This instrument consists of 15 items assessing five dimensions: personal, social, academic, occupational, and familial adjustment. Scoring is based on a five-point scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the first intervention group attend eight in-person group sessions of compassion-focused therapy based on mindfulness. Sessions are held once a week, each lasting 90 minutes. The content includes mindfulness training, self-compassion exercises, emotional acceptance, reduction of rumination, and practical activities. The therapy is conducted by a trained clinical psychologist.

Category

Behavior

2

Description

Control group: Participants in the control group do not receive any intervention and only take part in the pre-test and post-test assessments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranshahr University of Medical Sciences

Full name of responsible person

Fatemeh Firouzi

Street address

No. 24, End of Moallem Street, Shahr-e Deraz, Iranshahr County, Sistan and Baluchestan Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahmoud Imani

Street address

No. 24, End of Moallem Street, Shahr-e Deraz, Iranshahr County, Sistan and Baluchestan Province, Iran

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Fatemeh Firouzi

Position

Master's student in clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Islamic Azad University

Full name of responsible person
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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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Web page address

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
No - There is not 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
Individual participant data, full study protocol, statistical analysis plan, final clinical study report, analysis codes, and data dictionary will be shared. Participant data will be anonymized prior to sharing and will include scores related to the primary outcome variables (emotional failure and social adjustment), as well as basic demographic information. The informed consent form will not be published due to ethical considerations.

When the data will become available and for how long
Access will begin 6 months after the final study results are published.

To whom data/document is available
Study data and documents will be accessible to researchers affiliated with academic institutions, research centers, and scientific organizations. Individuals working in industry may also request access, provided they submit a clear and scientifically justified proposal. Access will be granted only after ethical review and approval.

Under which criteria data/document could be used
Use of the data and documents is permitted solely for academic and research purposes. Applicants must submit a clear research proposal, including study objectives, intended analysis type (such as statistical analysis, meta-analysis, or result verification), and institutional affiliation. Use of the data for commercial, promotional, or non-scientific purposes is not allowed. Access will be granted only after review and ethical approval by the research team. Redistribution or publication of the data or documents without prior coordination with the research team is prohibited.

From where data/document is obtainable
1. Email: Fatemeh Firouzi Email: fatemeh77firouzi@gmail.com 2. Address: Iranshahr University of Medical Sciences Research Department, Psychology Division Islamic Azad University of Zahedan Research Deputy, Department of Psychology 3. Phone:

Phone: 05437213891 For further information or coordination, initial contact via email is recommended.

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

Applicants must submit a written request via email, clearly stating the research objective, intended type of analysis, institutional affiliation, and the specific data or documents required. Requests will be reviewed by the research team and, if necessary, ethical approval will be obtained. Upon approval, the requested data or documents will be shared electronically within 2 to 4 weeks from the receipt of a complete application. Redistribution or reuse of the data without prior coordination with the research team is not permitted.

Comments