Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing of Effectiveness of Schema Mode Therapy Compared to Mentalization-Based Therapy on Shame, Guilt, Self-esteem, and Anxiety in Women who have experienced trauma

Protocol summary

Study aim

Comparing of Effectiveness of Schema Mode Therapy Compared to Mentalization-Based Therapy on Shame, Guilt, Self-esteem, and Anxiety in Women who have experienced trauma

Design

A randomized, parallel-group, open-label (unblinded), controlled clinical trial involving 48 patients. The `rand` function in Microsoft Excel will be used for randomization.

Settings and conduct

The statistical population for this study consists of all women with a history of trauma who visit the Shahed-Tolou Psychology and Counseling Clinic in Ahvaz during the specified study period. A convenience sampling method will be employed to select the sample. Following the selection of 48 participants—based on the study's inclusion and exclusion criteria—they will be randomly assigned to one of three groups: "Schema Therapy with a Mode-Based Approach" (Intervention Group 1), "Mentalization-Based Treatment" (Intervention Group 2), or a "Waiting List" (Control Group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 20 years and above, having trauma experience confirmed by standard instruments. Exclusion criteria: people who have psychosis, schizophrenia or severe personality disorders, people who have undergone similar psychological treatments or schema treatments in the last 6 months before the start of the research.

Intervention groups

Intervention Group 1: All women with a history of trauma who will receive the schema-mode therapy intervention. Intervention Group 2: All women with a history of trauma who will receive the mentalization-based treatment intervention. Control Group: All women with a history of trauma who will not receive any intervention.

Main outcome variables

Feelings of shame, feelings of guilt, self-esteem, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261019071495N1**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

Registration date

2026-10-22, 1405/07/30

Registrant information

Name

Maryam Daneshmand Gol Ayeneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3335 0172

Email address

mary.daanesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-11-06, 1405/08/15

Expected recruitment end date

2026-11-16, 1405/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of Effectiveness of Schema Mode Therapy Compared to Mentalization-Based Therapy on Shame, Guilt, Self-esteem, and Anxiety in Women who have experienced trauma

Public title

A Comparison of Two Mindfulness-Based Therapeutic Approaches in Reducing the Psychological Consequences of Trauma in Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20 and older. A history of trauma, confirmed via standardized instruments (such as a trauma questionnaire). A specific score on standardized scales measuring feelings of shame, guilt, low self-esteem, or anxiety.

Exclusion criteria:

Individuals suffering from psychosis, schizophrenia, or severe personality disorders. Individuals who have undergone similar psychological treatments or schema therapy within the six months prior to the commencement of the study. Substance or alcohol abuse that has affected the individual's mental state.

Age

From **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population for this study consists of all women with a history of trauma who visit the psychology and counseling clinic during the specified study period. A convenience sampling method will be employed to select the sample. Following the selection of 48 participants—based on the study's inclusion and exclusion criteria—they will be randomly assigned to one of three groups: "Schema Therapy with a Focus on Modes" (Intervention Group 1), "Mentalization-Based Treatment" (Intervention Group 2), or a "Waitlist" (Control Group). Randomization will be conducted using a permuted-block design (with block sizes of 4 and 6) by an independent statistician who is not involved in the study's implementation. The randomization sequence will be generated using the RAND function in Microsoft Excel and placed into opaque, sealed, and numbered envelopes to ensure that neither the researcher nor the participants are aware of the allocation sequence (allocation concealment). Envelopes will be opened—revealing the assigned group—only at the time each participant enters the study. To ensure the equivalence of baseline variables (such as anxiety levels and age), their distribution across the 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 the Islamic Azad University, Bushehr Branch

Street address

Velayat Building, beginning of Shahid Rais-Ali Delvari Boulevard, Shahrdar Square

City

Bushehr

Province

Boushehr

Postal code

7515895496

Approval date

2025-05-25, 1404/03/04

Ethics committee reference number

IR.BPUMS.REC.1404.123

Health conditions studied

1

Description of health condition studied

Psychological Consequences Resulting from Trauma

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Feelings of Shame and Guilt

Timepoint

1. Pre-test (before the intervention begins) 2. Post-test (immediately after the intervention period ends) 3. One-month follow-up after the intervention

Method of measurement

Measurement will be conducted using the shame and guilt scale developed by Cohen et al. (2011).

2

Description
Self-Esteem
Timepoint
1. Pre-test (before the intervention begins) 2. Post-test (immediately after the intervention period ends) 3. One-month follow-up after the intervention
Method of measurement
Measurement will be conducted using the Coopersmith Self-Esteem Inventory (1965).

3

Description
Anxiety
Timepoint
1. Pre-test (before the intervention begins) 2. Post-test (immediately after the intervention period ends) 3. One-month follow-up after the intervention
Method of measurement
Measurement will be conducted using the anxiety scale by Beck et al. (2001).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Mindfulness-based schema therapy intervention group: duration of each session: 90 minutes; Total number of sessions: 8 sessions; Sequence of sessions: twice a week; therapeutic tools used: this intervention relies heavily on rebuilding personality structures and activating inner sources of compassion. The main therapeutic tools include: therapeutic dialogue with a schema approach; experimental techniques; mental imagery exercises; and mindfulness exercises to separate modal states. The content of the different sessions is based on this: the first session: performing the pre-test, explaining the logic of mindfulness-based therapy and familiarizing with the concepts of primary maladaptive schemas in traumatized women; The second session: the participants are asked to identify their thinking and behavioral patterns in the face of trauma and recognize active schemas; The third session: using mental imagery techniques to access trauma memories and using mindfulness exercises to manage intense emotions; Session 4: Using the empty chair technique to face the "critic parent" and learn how to separate yourself from the modal states of shame and guilt; The fifth session: In this session, the reconstruction imaging technique will be used to respond to the emotional needs of the "damaged child" and to improve self-esteem; Sixth session: In this session, the pathology of the factors that cause the activation of self-punishment schemas and anxiety in women after trauma will be examined; Seventh session: teaching methods to deal with critical modal states and using compassion exercises to strengthen the "health parent" and calm down; The eighth session: Summing up the sessions, providing final suggestions for trauma management in daily life and finally, conducting the post-test and making a specific appointment for the follow-up test.
Category
Treatment - Other

2

Description
Intervention group 2: Mentalization-based treatment; duration per session: 90 minutes; total number of sessions: 8; frequency: twice weekly. Therapeutic tools: This intervention focuses on strengthening the capacity to observe the mind and fostering a non-judgmental acceptance of emotional experiences. Key therapeutic tools include: formal and informal mindfulness exercises; breathing and sensory-focus exercises; techniques for observing the mind; and emotional acceptance exercises designed to reduce automatic reactions to trauma. The content of the sessions is structured as follows: Session 1: Pre-assessment, introduction to the concept of mindfulness, and an explanation of the distinction between "being on autopilot" and "conscious presence" in the context of trauma management. Session 2: Instruction in breathing-focus exercises as a tool for grounding oneself in the present moment when facing anxiety. Session 3: Training in non-judgmental observation to identify thoughts and feelings related to shame and guilt without becoming entangled in them. Session 4: Body-focused mindfulness exercises to identify physical signs of anxiety and learn to observe these sensations without triggering defensive reactions. Session 5: Application of the "observing the mind" technique to create distance between the individual and traumatic thoughts, thereby reducing the intensity of guilt. Session 6: Exercises in accepting difficult emotions, learning how to engage with traumatic experiences without resorting to suppression or avoidance. Session 7: Integrating mindfulness with self-compassion to shift from a self-critical or self-centered perspective toward one characterized by acceptance and kindness. Session 8: Summarizing mindfulness strategies for daily life, offering suggestions for continuing practice at home, administering the post-test, and scheduling the follow-up assessment.
Category
Treatment - Other

3

Description
Control group: The control group will not receive any form of intervention during the conduct of the study; however, to prevent threats to the study's internal validity—such as compensatory rivalry or demoralization—they will receive the interventions after the data collection phase.
Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahed Tolou Counseling and Psychological Center

Full name of responsible person
Maryam Daneshmand Gol Ayneh

Street address
South Amir Kabir Street, Enghelab Boulevard, Enghelab District

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Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Rouhollah Ershadi

Street address
Velayat Bldg., Start of Shahid Rais-Ali Delvari Blvd., Shahrdari Sq.

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RouhallahErshadi@iau.ac.ir

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
Maryam Daneshmand Gol Ayneh

Position
Ph.D. Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Position
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Latest degree
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Other areas of specialty/work
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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