Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effectiveness of compassion therapy on depression, functional flexibility, self-differentiation, and perceived social support in women with depression referring to psychological counseling centers

Protocol summary

Study aim
Studying the effectiveness of compassion therapy on depression, functional flexibility, self-differentiation, and perceived social support in women with depression referring to psychological counseling centers

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population of this study includes all female patients with depressive disorder who will refer to Amin Psychological Counseling and Services Center in Ahvaz for treatment within the specified time period for the study. In the sample selection stage, the available sampling method will be used. After selecting the samples to a volume of 40 people based on the study's entry and exit criteria, the participants will be randomly assigned to two groups: "compassionate treatment" (intervention group) and "waiting list" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 30 to 45 years, scoring between 20 and 28 on the Beck Depression Inventory, having a history of depressive disorder for a maximum of 2 years, undergoing medication for depression Exclusion criteria: Participating in other psychotherapy sessions 3 months prior to the study, unwillingness to participate in the study

Intervention groups
Intervention group: All individuals who will receive self-compassion therapy. The sessions of this study will be designed based on the Compassion-Focused Therapy book, which is based on the Compassion-Focused Therapy Package based on Gilbert's concepts (2010), which will be conducted in 8 90-minute sessions. Control group: All individuals who will not receive any intervention.

Main outcome variables
Depression, functional flexibility, self-differentiation, and perceived social support

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260712070153N1**
Registration date: **2026-07-15, 1405/04/24**
Registration timing: **prospective**

Last update: **2026-07-15, 1405/04/24**
Update count: **0**

Registration date
2026-07-15, 1405/04/24

Registrant information
Name
Maryam Torfi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3379 9217
Email address
maryamtorfi48@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-08-06, 1405/05/15
Expected recruitment end date
2026-08-22, 1405/05/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effectiveness of compassion therapy on depression, functional flexibility, self-differentiation, and perceived social support in women with depression referring to psychological counseling centers

Public title
The effectiveness of compassion on psychological components of women with depression
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 30 to 45 years Scoring between 20 and 28 on the Beck Depression Inventory Having a maximum of 2 years of history of depressive disorder Undergoing medication for depression.
Exclusion criteria:
Participation in other psychotherapy sessions 3 months before the study Unwillingness to participate in the study
Age
From **30 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistical population of this study includes all female patients with depressive disorder who will refer to the counseling and psychological services center for treatment within the specified time period for the study. In the sample selection stage, the available sampling method will be used. In such a way that people who are definitely diagnosed with depression by experts and based on the fifth edition of the classification of mental disorders using a structured checklist will be selected. After selecting the samples to a volume of 40 people based on the study's entry and exit criteria, the participants will be randomly assigned to two groups: "compassionate treatment" (intervention group) and "waiting list" (control group). Randomization will be performed using the random block method with variable sizes (4 and 6 people) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and numbered envelopes so that the researcher and participants are not aware of the allocation sequence (allocation concealment). Opening the envelope and informing the group allocation will only be done when each participant enters the study. To ensure the equality of the baseline variables (such as anxiety level, age, and length of marriage), their distribution in the two groups will be examined during the statistical analysis stage.
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, Ahvaz Branch
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Approval date
2026-06-30, 1405/04/09
Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.389

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Depression
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 method of measurement will be the Beck Depression

Inventory (1961).

2

Description
Functional Flexibility
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 using the Connor and Davidson (2003) Functional Flexibility Questionnaire.

3

Description
Self-Differentiation
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 Skowron and Friedlander (1998) differentiation questionnaire.

4

Description
Perceived Social Support
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 method of measurement will be Zimmet et al.'s (1988) multidimensional scale of perceived social support.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Compassion-based therapy; Duration of each session: 90 minutes; Total number of sessions: 8 sessions; Sequence of sessions: twice a week; Therapeutic tools used: This intervention relies on the reconstruction of emotional regulation systems. The main tools include the following: Psychological training. Mindfulness exercises. Guided imagery exercises. Writing techniques, body-focusing exercises. Session content: First session: Pre-test; Psychological training about the structure of the brain and emotional systems; Explanation of the concept of compassion and its distinction from self-compassion and compassion. Second session: Identification of the "inner critic"; Examination of self-deprecating thought patterns and the harms caused by self-differentiation in women. Third session: Training in mindfulness exercises to observe negative thoughts; Introduction of the "soothing breathing" technique; Initial exercises to activate the relief system to reduce the severity of depressive symptoms. Fourth session: Training in compassionate imagery skills; Practice creating a "compassionate personality" to deal with self-blame and increase functional flexibility. Session five: Writing exercise; Using emotional discharge technique to process past painful experiences with a compassion-based approach. Session six: Examining barriers to compassion; Strengthening perceived social support through compassion exercises in interpersonal relationships. Session seven: Teaching strategies to deal with negative automatic thoughts using a compassion approach; Deep relaxation exercises and consolidating learned skills in daily life. Session eight: General summary; Reviewing mental health maintenance programs; Conducting a post-test and determining the time for a follow-up test to assess the durability of the intervention effects.
Category
Treatment - Other

2

Description
Control group: The control group will not receive any intervention during the research. However, to avoid factors that threaten the internal validity of the research, such as compensatory competition from the control group or demoralization, they will be assured that they will receive self-compassion therapy at the next visit (after data collection).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Psychological Counseling and Services Center, Ahvaz
Full name of responsible person
Maryam Torfi
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Phone
+98 61 3334 8421
Email
Maryamtorfi48@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Egdarnezhad
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Phone
+98 61 3334 8421
Email
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
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 Torfi
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 161, Rad St., between Holali and Eznavi, Kouy-e Enqelab
City
Ahvaz
Province
Khouzestan
Postal code
6144936535
Phone
+98 61 3379 9217
Email
Maryamtorfi48@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Torfi
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 161, Rad St., between Holali and Eznavi, Kouy-e Enqelab
City
Ahvaz
Province
Khouzestan
Postal code
6144936535
Phone
+98 61 3379 9217
Email
Maryamtorfi48@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Torfi
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 161, Rad St., between Holali and Eznavi, Kouy-e Enqelab
City
Ahvaz
Province
Khouzestan
Postal code
6144936535
Phone
+98 61 3379 9217
Email
Maryamtorfi48@gmail.com

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