Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of self-care and self-compassion therapy on mood alexithymia, perceived stress, ego strength, and quality of life in psychosomatic patients

Protocol summary

Study aim
Comparing the effectiveness of self-care and self-compassion therapy on mood alexithymia, perceived stress, ego strength, and quality of life in psychosomatic patients

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 45 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population of this study includes all patients with psychosomatic disorders referring to the Rayan Psychology and Counseling Clinic in Ahvaz who will refer to the clinic within the specified time period for the study. In the sample selection stage, the convenience sampling method will be used. After selecting the samples to a volume of 45 people based on the study's entry and exit criteria, the participants will be randomly assigned to three groups: "self-treatment" (intervention group 1), "self-compassion therapy" (intervention group 2), and "waiting list" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmation of psychosomatic diagnosis based on clinical interview by an experienced psychologist or psychiatrist, age range between 25 and 40 years. Exclusion criteria: Simultaneous participation in other psychotherapy interventions or psychological training courses, unwillingness to participate in the study

Intervention groups
Intervention group 1: All individuals who will receive self-care therapy. Intervention group 2: All individuals who will receive self-compassion therapy. Control group: All individuals who will receive no intervention.

Main outcome variables
Alexithymia, Perceived Stress, Ego Strength, Life Well-Being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260901070861N1**
Registration date: **2026-09-22, 1405/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-22, 1405/06/31**
Update count: **0**

Registration date
2026-09-22, 1405/06/31

Registrant information

Name
Sara Mousawi

Name of organization / entity

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Iran (Islamic Republic of)

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sara.mousavi4146@iau.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-09-21, 1405/06/30

Expected recruitment end date
2026-10-02, 1405/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of self-care and self-compassion therapy on mood alexithymia, perceived stress, ego strength, and quality of life in psychosomatic patients

Public title
Investigating the effect of self-focused therapies on improving mental health in patients with psychosomatic problems

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1. Confirmation of a psychosomatic diagnosis based on a clinical interview by an experienced psychologist or psychiatrist Having an age range between 25 and 40 years

Exclusion criteria:
Concurrent participation in other psychotherapy interventions or psychological training courses 3 months prior to the study Unwillingness to participate in the study

Age
From **25 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The statistical population of this study includes all patients with psychosomatic disorders who refer to the psychology and counseling clinic and who will refer to the clinic 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 45 people based on the study's entry and exit criteria, the participants will be randomly assigned to three groups: "self-treatment" (intervention group 1), "self-compassion treatment" (intervention group 2), 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). The envelope will be opened and the allocation group will be informed only when each participant enters the study. To ensure the equality of baseline variables (such as anxiety level and age), 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 of Ahvaz Branch

Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Approval date
2026-03-16, 1404/12/25

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.017

Health conditions studied

1

Description of health condition studied
Physical disorders of psychological origin

ICD-10 code
F45

ICD-10 code description
Body dysmorphic disorder

Primary outcomes

1

Description
Alexithymia

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 Toronto Taylor Alexithymia Questionnaire (1989).

2

Description
Perceived Stress

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 Cohen et al. (1983) Perceived Stress Scale.

3

Description

Ego Strength

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 Mann-Flack and Narakmeh (2002) strength scale.

4

Description

Life Well-Being

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 through the Bio-Benefit Questionnaire by Joharifard (2024).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Self-discipline; Duration of each session: 90 minutes; Total number of sessions: 14 sessions; Sequence of sessions: Twice a week; Therapeutic tools used: This intervention focuses on activating internal resources, rebuilding lifestyle, and emotional self-care. The main tools include: guided therapeutic dialogue, cognitive-behavioral training, body care exercises, stress management techniques, and rebuilding my strength. Session content: Session 1: Conducting a pre-test; Explaining the therapeutic logic; Getting to know the concepts of "self-discipline" and its role in improving the psychosomatic state. Session 2: Identifying basic needs; Examining the current lifestyle and its difference from the ideal self-discipline pattern. Session 3: Body awareness skills; Practicing identifying physical tensions. Session 4: Emotional analysis; Training in naming emotions and distinguishing between physical and mental feelings. Session 5: Assessing thoughts; Identifying dysfunctional beliefs that lead to ignoring one's own needs. Session 6: Breathing and relaxation techniques; Abdominal breathing training for managing perceived stress. Session 7: Managing stress in daily life; Identifying stress triggers and effective coping strategies. Session 8: Strengthening "my resilience"; Examining personal strengths and increasing self-esteem and self-efficacy. Session 9: Teaching assertiveness skills; Learning to say "no" and setting healthy boundaries in relationships to reduce psychological stress. Session 10: Managing negative emotions; Using writing techniques to express pent-up emotions. Session 11: Improving well-being; Planning for enjoyable and meaningful activities. Session 12: Pathology of barriers to self-care; Examining individual fears and resistance to lifestyle changes. Session 13: Consolidating skills; Reviewing methods for dealing with slippage and continuing exercises in critical situations. Session 14: Final summary; Presenting a plan for continuing self-care; Conducting a post-test and determining the timing of the follow-up test.

Category

Treatment - Other

2

Description

Intervention group 2: Compassion-focused 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 heavily on activating emotional regulation systems and internal resources of compassion. The main therapeutic tools include: guided therapeutic dialogue; mindfulness exercises; self-compassion imagery exercises; reciprocal compassion imagery exercises. Session content: Session 1: Pre-test; explanation of the logic of compassion-focused therapy and understanding the concepts of self-compassion and compassion for others in order to reduce psychosomatic tensions. Session 2: Identification of critical mental and behavioral patterns that the individual has towards himself; examination of the individual's way of thinking and behaving in the face of physical and psychological pain. Session 3: Training in compassionate imagery skills; practicing mindfulness to connect with oneself and using soothing breathing techniques to regulate physiological responses. Session 4: Using mindfulness techniques to focus on bodily experiences; teaching how to express emotional empathy towards personal suffering and repressed emotions. Session 5: Technique for writing a “compassionate letter”; enhancing the capacity for self-compassion by emotionally releasing past trauma and accepting shared humanity. Session 6: Pathology of obstacles and factors that create “fear of compassion”; examining internal fears and repulsions towards expressing kindness to oneself. Session 7: Teaching methods for dealing with resistance to compassion; strengthening self-compassion during times of peak stress and using relaxation techniques. Session 8: Summarizing the sessions, providing final suggestions for consolidating skills; administering the post-test and determining the timing for administering the follow-up test.

Category

Treatment - Other

3

Description
Control group: The control group will not receive any intervention during the research, but will receive the treatment 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
Rayan Psychological Counseling and Clinic Center, Ahvaz
Full name of responsible person
Sara Mousavi
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Between 4th and 5th Street, Kianpars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Egdarnezhad
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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
Sara Mousavi
Position
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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