Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Effectiveness of Compassion-Focused Group Therapy and Schema-Informed Acceptance and Commitment Group Therapy on Depression, Internalized Shame, Interpersonal Problems, Early Maladaptive Schemas, and Quality of Life in Individuals Who Have Experienced Romantic Relationship Dissolution: A Three-Arm Randomized Clinical Trial

Protocol summary

Study aim

To compare the effectiveness of compassion-focused and schema-informed ACT group therapies, each versus waitlist control, on depression, internalized shame, interpersonal problems, maladaptive schemas, and quality of life in individuals with romantic relationship breakup.

Design

Randomized, three-arm, parallel-group trial with waitlist control, 1:1:1 allocation, 45 participants (15/group); simple randomization via Excel RAND by an independent researcher; outcome assessor and analyst blinded.

Settings and conduct

This randomized, three-arm clinical trial will be conducted at Shahid Beheshti Hospital, Zanjan, among individuals over 18 with a history of romantic relationship breakup. After screening (SCID and pre-test), volunteers will be randomized 1:1:1 into three groups (Compassion-Focused Therapy, Schema-Informed ACT, waitlist control). Treatments will be delivered by trained therapists under supervision, with sessions recorded. All participants will be assessed at post-test and 6-month follow-up. The outcome assessor and statistical analyst will be blinded; participants and therapists will not.

Participants/Inclusion and exclusion criteria

Inclusion: age 18–40; breakup within past 6 months (relationship ≥3 months); score above cutoff on Post-Separation Distress Scale; BDI-II≥14; adequate literacy. Non-inclusion: concurrent psychological treatment.

Intervention groups

Compassion-Focused: 8 weekly group sessions (90 min) based on The Compassionate Mind Workbook. Schema-Informed ACT: 10 weekly group sessions (90 min) based on the Ciarrochi program. Control: waitlist, no active treatment; questionnaires only; receives effective treatment after study.

Main outcome variables

Depression; internalized shame; early maladaptive schemas; interpersonal problems; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260913071035N1**
Registration date: **2026-09-14, 1405/06/23**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **0**

Registration date

2026-09-14, 1405/06/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-09-19, 1405/06/28
Expected recruitment end date
2026-09-23, 1405/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effectiveness of Compassion-Focused Group Therapy and Schema-Informed Acceptance and Commitment Group Therapy on Depression, Internalized Shame, Interpersonal Problems, Early Maladaptive Schemas, and Quality of Life in Individuals Who Have Experienced Romantic Relationship Dissolution: A Three-Arm Randomized Clinical Trial

Public title
Comparing the effectiveness of compassion-focused therapy and acceptance and commitment therapy in people who have experienced emotional breakdown
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Score above the cutoff point (16) on the Post-Breakup Distress Scale. 2. Duration of the relationship at least 3 months before the breakup. 3. Experience of emotional breakdown in the past 6 months. 4. Having sufficient literacy to complete the questionnaires. 5. Age range 18 to 40 years. 6. Not receiving concurrent psychological treatment. 7. Score at least 14 on the Beck Depression Inventory (BDI-II)
Exclusion criteria:
Receiving psychotherapy or other psychological intervention at the start of the study Experiencing a severe stressful event (such as bereavement or a serious accident) or having an acute medical illness (such as a heart attack or stroke) Having severe symptoms of depression or suicidal thoughts that require immediate intervention Failure to cooperate at any stage of the research or failure to complete the questionnaires
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
After recruiting volunteers, the implementation process is as follows: Screening and initial assessment. Volunteers are assessed with a short interview and complete self-report questionnaires (pre-test). Those who meet the entry criteria are selected to enter the random assignment stage. In the next step, random assignment is performed. The random assignment sequence is generated using the RAND function in Excel software and simple randomization. In one column, 15 numbers code 1 (compassion-focused therapy group), 15 numbers code 2 (schema-aware acceptance and commitment therapy), and 15 numbers code 3 (control group) are entered, and 45 random numbers are generated in the adjacent column with the RAND function. The data is sorted in descending order based on the random number column, and the order of codes 1, 2, and 3 is determined completely randomly. This sequence is stored in an encrypted file.An independent researcher who has no role in administering the treatment generates the sequence and announces each participant's allocation code after they enter the study. Thus, the principal investigator who enters the participants into the study is unaware of the allocation sequence
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding Procedures in This Study Due to the nature of the group-based psychological interventions, full blinding of all parties involved was not feasible. The blinding status of each role is described below: Participants: Not blinded. Each participant was aware from the outset of their allocation to one of the two active intervention groups (Compassion-Focused Group Therapy or Schema-Informed Acceptance and Commitment Therapy) or to the waitlist control group, as the nature of group-based treatment (attendance versus non-attendance at sessions) precluded participant blinding. All participants, including those in the waitlist control group, were informed during the informed consent process, prior to enrollment, that they would be randomly allocated to one of three groups. Principal Investigator: Not blinded. The principal investigator became aware of group allocation after the randomization process, given responsibility for coordinating intervention delivery. However, the principal investigator had no role in generating the randomization sequence (this was delegated to an independent researcher) and had no involvement in outcome assessment at post-test or follow-up, to prevent influence on results. Therapists (intervention delivery personnel): Not blinded. The therapists (the principal investigator's student and a clinical psychology graduate student) were necessarily aware of the treatment protocol they delivered but had no role in outcome data collection or statistical analysis. Data collectors and outcome assessors: Blinded. The outcome assessor was an individual independent of the therapy team and the principal investigator, responsible for conducting the structured clinical interview (SCID) and administering self-report questionnaires at post-test and 6-month follow-up. This individual did not attend therapy sessions, had no access to the randomization allocation file, and participants were instructed to refrain from disclosing their group assignment or session content to the assessor. Statistical analyst: Blinded. Data

were labeled with de-identified numeric codes (without group names or intervention type) prior to being provided to the statistical analyst. Primary analyses were conducted without knowledge of the correspondence between codes and group names; the decoding key was released to the analyst only after completion of the primary analyses. Data Safety and Monitoring Board (DSMB): Given the small scale of this trial (single-center, limited sample size) and the low-risk nature of the psychological interventions, a formal DSMB was not established; safety and procedural oversight was instead conducted by the faculty supervisor and the university research ethics committee. [If a DSMB exists in your actual study, its blinding status must be reported in the same manner.] Manuscript preparers: During preparation of the final report and descriptive analysis, the authors had access to the correspondence between codes and group names, as interpretation of findings required knowledge of intervention type. However, the primary (hypothesis-driven) statistical analyses were conducted and reported by the independent analyst prior to unblinding, to prevent biased interpretation. Important ethical note: All participants, including those in the waitlist control group, were fully informed—prior to enrollment—of the study's research nature, the possibility of not receiving active treatment during the study period, and the guarantee of receiving effective treatment after study completion, and provided written informed consent. At no stage were participants left unaware of their participation in the research.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

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Zanjan, Ostad Dr. Yousef Sobouti Boulevard, Zanjan University of Medical Sciences

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zanjan

Province

Zanjan

Postal code

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Approval date

2026-08-31, 1405/06/09

Ethics committee reference number

IR.ZUMS.REC.1405.130

Health conditions studied

1

Description of health condition studied

Individuals with a history of romantic relationship failure and depression

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

Primary outcomes

1

Description

Depression

Timepoint

Before the start of the intervention, after the completion of the intervention, and 6 months after the end of the intervention

Method of measurement

Depression:Measured using the Beck Depression Inventory-Second Edition (BDI-II); the Persian version was validated by Ghassemzadeh et al. (2005).

2

Description

interpersonal problems

Timepoint

Before the start of the intervention, after the completion of the intervention, and 6 months after the end of the intervention

Method of measurement

Interpersonal Problems:Measured using the short-form Inventory of Interpersonal Problems (IIP-32); the Persian version was validated by Fath et al. (2013).

3

Description

early maladaptive schemas

Timepoint

Before the start of the intervention, after the completion of the intervention, and 6 months after the end of the intervention

Method of measurement

Early Maladaptive Schemas:Measured using the Young Schema Questionnaire-Short Form, 75 items (YSQ-SF); the Persian version was validated by Ghahari et al. (2020).

4

Description

internalized shame

Timepoint

Before the start of the intervention, after the completion of the intervention, and 6 months after the end of the intervention

Method of measurement
Internalized Shame:Measured using Cook's Internalized Shame Scale (ISS); the Persian version was validated by Rajabi and Abbasi (2011).

Secondary outcomes

1

Description
quality of life
Timepoint
Before the start of the intervention, after the completion of the intervention, and 6 months after the end of the intervention
Method of measurement
Measured using the 12-item Short Form Health Survey (SF-12).

Intervention groups

1

Description
Intervention group: Intervention 1: Compassion-Focused Group TherapyAn 8-session weekly group protocol (90 minutes/session) based on The Compassionate Mind Workbook (Irons & Beaumont), aimed at reducing internalized shame and depression through cultivating self-compassion and reducing self-criticism
Category
Treatment - Other

2

Description
Intervention 2: Schema-Informed Acceptance and Commitment Therapy A 10-session weekly group protocol (90minutes/session) based on the Ciarrochi program, combining core ACT processes (acceptance, cognitive defusion, values) with identification of early maladaptive schemas, aimed at increasing psychological flexibility.
Category
Treatment - Other

3

Description
Control group: This group receives no active therapeutic intervention during the study period (including the intervention phase and the 6-month follow-up) and only completes the study questionnaires (Beck Depression Inventory, Internalized Shame Scale, Young Schema Questionnaire, Inventory of Interpersonal Problems, and SF-12 Quality of Life questionnaire) at pre-test, post-test, and 6-month follow-up assessments. Upon completion of the follow-up phase, participants in this group will receive whichever of the two active treatments is found to be more effective.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Counseling Center of Zanjan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zanjan University of Medical Sciences
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Given the sensitivity of the psychological data collected (including scores on depression, internalized shame, and maladaptive schemas) and the relatively small sample size of this study (n=45) conducted within a geographically limited population (Zanjan Province), there is a meaningful risk of participant re-identification even after removal of direct identifiers. Furthermore, the informed consent obtained from participants does not include explicit authorization for the public sharing of individual participant data (IPD) with external researchers. Accordingly, there is currently no plan to make the individual participant data from this study publicly available.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The final Clinical Study Report and the Informed Consent Form used in this trial. The Clinical Study Report includes the complete methodology and the descriptive and inferential findings of the study, while the Informed Consent Form includes the full text presented to participants to obtain informed consent. Neither document contains any individually identifiable participant data.
When the data will become available and for how

long

6 months after results are published

To whom data/document is available

These documents will be accessible to any interested member of the public, without restriction based on institutional or professional affiliation (including academic researchers, industry professionals, or other interested individuals).

Under which criteria data/document could be used

These documents will be made available solely for informational, educational, and review purposes. Applicants must briefly state the purpose of their request, and proper citation of the source is required in any use or reference. Commercial use of these documents without prior coordination with the principal investigator is not permitted.

From where data/document is obtainable

Applicants may contact Ms. Elham Didehban (PhD candidate in Clinical Psychology, principal thesis investigator) via email at elhamdidehban1996@gmail.com. In case of no response, applicants may alternatively contact the Department of Psychiatry and Clinical Psychology, Shahid Beheshti Hospital, Zanjan.

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

Applicants submit their request via email, stating the intended purpose of use. The request will be reviewed and responded to within a maximum of two business weeks. Upon approval, the requested documents will be sent to the applicant via email or a download link.

Comments