Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of reality therapy on distress tolerance and rumination about loss in students with emotional breakdown

Protocol summary

Study aim
Determining the effectiveness of reality therapy on distress tolerance and rumination about loss in students with emotional breakdown

Design
A randomized, placebo-controlled clinical trial on 30 female students with emotional breakdown. Simple randomization was used for randomization.

Settings and conduct
This study is being conducted at Semnan Branch of Islamic Azad University and involves students with emotional breakdown. Participants are randomly divided into two groups: the experimental group that receives the reality therapy intervention and the control group that only follows their routine programs and usual care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: experiencing emotional breakdown in the past three months, age between 18 and 35 years, high scores on rumination and distress tolerance measures, and willingness and commitment to participate in all treatment intervention sessions. Exclusion criteria: having severe psychiatric disorders, taking effective psychiatric medications, and experiencing severe stressful events in the past three months.

Intervention groups
In this study, the intervention group will undergo reality therapy intervention. This intervention will be held in 5 120-minute sessions, held weekly. The content of the sessions is designed based on the principles and techniques of reality therapy. The control group will not receive any specific therapeutic intervention and will only receive usual and standard care, which includes general counseling services or other standard services available.

Main outcome variables
Tolerating turmoil, ruminating about loss

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250106064293N1**
Registration date: **2025-01-27, 1403/11/08**
Registration timing: **prospective**

Last update: **2025-01-27, 1403/11/08**
Update count: **0**

Registration date
2025-01-27, 1403/11/08

Registrant information

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Name of organization / entity
Islamic Azad University, Semnan Branch

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-14, 1403/11/26

Expected recruitment end date
2025-03-16, 1403/12/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of reality therapy on distress tolerance and rumination about loss in students with emotional breakdown

Public title
The effect of reality therapy on distress tolerance and rumination about loss in students with emotional breakdown

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Experience of emotional breakdown in the past three months based on student self-report. Age between 18 and 35 years. Obtaining high scores on rumination and disturbance tolerance assessment tools (based on the specified cutoff point). Willingness and commitment to participate in all therapeutic intervention sessions. No use of other psychological or psychiatric treatments during the research period.

Exclusion criteria:
Having severe psychiatric disorders such as bipolar disorder or schizophrenia (based on medical diagnosis history). Taking psychiatric medications that may affect tolerance to agitation or rumination. Experiencing other severe stressful events in the past three months (such as the loss of a loved one, a serious accident, or job loss). The presence of any acute or chronic physical conditions that may prevent effective participation in intervention sessions.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method was used to randomize participants. After selecting 30 people as a sample, each participant was randomly assigned to one of two intervention groups (real therapy) or control group. For this purpose, the numbers 1 to 30 were assigned to the participants and, using a random number table or random number generation software, the numbers corresponding to each participant were selected and assigned to one of the two groups. Randomization was performed individually, meaning that each participant was independently assigned to the intervention or control group. This method ensures that there is no bias in the assignment of individuals to the groups and that each person has an equal chance of being placed in each of the groups.

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 Semnan Azad University

Street address
Islamic Azad University, University Town, Semnan, Iran

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Province
Semnan

Postal code
3513137111

Approval date
2024-12-30, 1403/10/10

Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.097

Health conditions studied

1

Description of health condition studied
Emotional Breakdown

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Distress Tolerance

Timepoint
Before the start of the intervention and after completing 5 intervention sessions

Method of measurement
Simons and Gahr's Distress Tolerance Questionnaire (2005)

2

Description
Rumination about loss

Timepoint
Before the start of the intervention and after completing 5 intervention sessions

Method of measurement
Rumination Questionnaire Eisma et al (2014)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will undergo a reality therapy intervention, which will be held in 5 120-minute sessions in a month. This intervention is designed to increase tolerance for distress and reduce rumination about loss caused by emotional breakdown. Initially, the feelings caused by loss and emotional breakdown are identified and accepted, and clients are introduced to the importance of the realities in life and their personal responsibilities. Then, reality therapy techniques are taught, including making changes in attitudes and beliefs, encouraging focus on present and future decisions, and strengthening a sense of meaning in life. In the next stages, clients will learn skills to manage and reduce rumination and mental turmoil through cognitive and behavioral strategies. Finally, the changes are consolidated and exercises to maintain the gains and prevent a return to previous patterns are made available to clients.

Category

Treatment - Other

2

Description

Control group: This group will not receive any treatment related to the study and will serve as a benchmark for comparison with the experimental group. Members of this group will simply follow the routine programs and standard care that they would normally receive. No program or intervention related to reality therapy will be provided to this group during the study. The goal is to keep the control group conditions unchanged so that the effects of the reality therapy intervention on distress tolerance and rumination can be accurately and reliably examined.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

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Islamic Azad University, Semnan Branch

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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, Semnan Branch

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, Semnan Branch

Full name of responsible person
Delara Doustmohammadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
Yes - There is 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
Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.
When the data will become available and for how long
The data will be available one month after the results are published and after personally identifiable information has been removed.
To whom data/document is available
Research data and documentation will be available to researchers and scholars working in reputable academic and scientific institutions. In addition, researchers working in industry related to the research topic can also apply to receive data and documentation.
Under which criteria data/document could be used
For the purpose of studying or conducting research, citing the source.
From where data/document is obtainable
If you need data, please contact Jb.delara2000@gmail.com.
What processes are involved for a request to access data/document
After receiving the request and reviewing it by the principal investigator, the data will be sent to the applicant within a maximum of one week, along with a commitment not to publish the data without the name of the principal investigator.
Comments