Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of cognitive therapy based on mindfulness in reducing rumination and negative spontaneous thoughts in people suffering from depression and anxiety disorders in female students

Protocol summary

Study aim
The effectiveness of mindfulness-based cognitive therapy in reducing rumination in patients with depression and anxiety disorders

Design
The type of semi-experimental study, with a control group, with parallel groups, sample size of 24 people, two parallel groups of 12 people, not blinded

Settings and conduct
Research Location: Raz Happiness Clinic Neshabur The study was conducted on 24 students aged 18 to 25 years (in two groups of 12). The first four sessions of MBCT therapy were devoted to teaching mindfulness techniques and non-judgmental awareness of present-moment internal experiences. In the next four sessions of MBCT therapy, the therapist's main goal was to provide the client with the necessary tools to prevent the relapse of the psychological disorder they were suffering from. Non-random assignment to intervention and control groups and blinding were not considered by the researchers.

Participants/Inclusion and exclusion criteria
Co-occurring psychotic and substance use disorders

Intervention groups
Twenty-four participants were randomly assigned to two groups. The experimental group received eight sessions of mindfulness-based cognitive therapy, while the control group received their usual treatment. The Rumination Response Scale was administered at pre-test, post-test, and follow-up for both groups.

Main outcome variables
1. Independent variables: Efficacy of mindfulness-based cognitive therapy. 2. Dependent variables: Reduction of rumination and negative automatic thoughts. 3. Background variables: Age, Parental education level, Family income level. 4. Confounding variables: Access to psychotherapy, Misfit with the treatment method, Lack of family support and Unsatisfactory family relationships.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231009059669N1**
Registration date: **2024-03-22, 1403/01/03**
Registration timing: **retrospective**

Last update: **2024-03-22, 1403/01/03**
Update count: **0**

Registration date
2024-03-22, 1403/01/03

Registrant information
Name
fatemeh sanati
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 4263 3741
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-12, 1402/07/20
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of cognitive therapy based on mindfulness in reducing rumination and negative spontaneous thoughts in people suffering from depression and anxiety disorders in female students

Public title
Efficacy of mindfulness-based cognitive therapy in reducing rumination and negative automatic thoughts in individuals with depression and anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 18 to 25 A student living in the dormitory of Neishabur University Obtaining the minimum scores required to diagnose depression and anxiety in the DASS-21 test
Exclusion criteria:
History of bipolar disorders and psychotic disorders History of dependence or substance-related disorders

Age
From **18 years** old to **25 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 of Medical Sciences
Street address
5 km of Semnan, Damghan road
City
Semnan
Province
Semnan
Postal code
3513137111
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.IAU.SEMNAN.REC.1402.026

Health conditions studied

1

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

2

Description of health condition studied
Social Anxiety Disorder
ICD-10 code
F40.1
ICD-10 code description
Social phobias

Primary outcomes

1

Description
High score of depression
Timepoint
Before the beginning of the therapeutic intervention of the first session, after the completion of the therapeutic intervention of the eighth session
Method of measurement
Depression and Anxiety Questionnaire (DASS-21)

2

Description
Anxiety in DASS questionnaire
Timepoint
Before the beginning of the therapeutic intervention of the first session, after the completion of the therapeutic intervention of the eighth session
Method of measurement
Depression and Anxiety Questionnaire (DASS-21)

Secondary outcomes

1

Description
Scores obtained in the rumination test
Timepoint
Before the beginning of the therapeutic intervention of the first session, after the completion of the therapeutic

intervention of the eighth session

Method of measurement

Rumination response scale questionnaire

Intervention groups

1

Description

Intervention group: The sample group in this research includes 24 students suffering from depression and anxiety, of which 12 subjects were included in the experimental group, who, in addition to the usual treatment, also participated in cognitive therapy classes based on mindfulness, group (MBCT) And another 12 people were in the control group who did not receive treatment. The experimental group participated in 8 sessions of cognitive therapy based on mindfulness along with their usual treatment. These classes are held once a week for 2 hours each time. The control group continued their usual treatment. After the completion of eight treatment sessions, the research tool, that is, the scale of rumination responses, was implemented in the post-test stage for both groups. This measurement was done in a simultaneous session for both groups. After 8 weeks, in the follow-up phase, both groups will be measured again with the rumination response scale.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Secret Clinic (Secret of Happiness)

Full name of responsible person

Seyed javad razavi

Street address

No. 15 Khordad Street, Corner of 7th Khordad, Pasargad Complex, 3rd Floor, Raaz Counseling and Psychological Services Center (Secret of Happiness)

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Razavi Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Karim Sohrabi

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Province

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3711135131

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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

Semnan 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

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Fatemeh sanati

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

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Person responsible for updating data

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available