Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of Mindfulness-based Cognitive Therapy on Repetitive Negative Thoughts and Anxiety and Depression in Female Adolescents with comorbid Anxiety and Depression Disorders

Protocol summary

Study aim
Investigating the effectiveness of cognitive therapy based on mindfulness on repetitive negative thoughts and anxiety and depression in adolescent girls suffering from anxiety and depression disorders.

Design
The research method will be semi-experimental and using a pre-test-post-test design with a control group.

Settings and conduct
Randomly selecting a second secondary school and distributing questionnaires of repetitive negative thoughts, anxiety and depression, obtaining the research sample, placing them randomly in two intervention and control groups, placing the experimental group in a ten-session therapeutic intervention. And finally taking post-test results from both groups.

Participants/Inclusion and exclusion criteria
All students studying in the second level of secondary school in Taybad city in the year 2022. The research sample includes 40 of these students who meet the entry and exit criteria of the study. Entry criteria: presence of anxiety disorder and depression, consent to participate in the research. Criteria for people to be excluded from the study: receiving any type of psychotherapy or drug therapy at the same time for the desired emotional problems, having received cognitive therapy based on mindfulness so far, the person's unwillingness to continue the treatment process, change in the amount and type of psychiatric drugs during the research.

Intervention groups
In this research, the sample group will be subjected to the cognitive therapy protocol based on mindfulness once a week, in 10 one-hour sessions. The sample group includes female students with similar anxiety and depression disorders who will undergo mindfulness-based treatment. The control group will not receive any intervention.

Main outcome variables
Primary result variable: repetitive negative thoughts
Secondary result variable: anxiety and depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220706055396N1**
Registration date: **2022-08-10, 1401/05/19**
Registration timing: **prospective**

Last update: **2022-08-10, 1401/05/19**
Update count: **0**

Registration date
2022-08-10, 1401/05/19

Registrant information
Name
Neda BazrAfshan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-16, 1401/05/25
Expected recruitment end date
2022-08-22, 1401/05/31
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of Mindfulness-based Cognitive Therapy on Repetitive Negative Thoughts and Anxiety and Depression in Female Adolescents with comorbid Anxiety and Depression Disorders

Public title
The Effect of MBCT On Female Adolescents' Repetitive Negative Thoughts, Anxiety and Depression
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The simultaneous presence of clinically significant anxiety disorder and depression, based on questionnaires and interviews consent to participate in the research
Exclusion criteria:
Receiving any type of psychotherapy or medication at the same time for the desired emotional problems
Receiving cognitive therapy based on mindfulness so far participant's unwillingness to continue the treatment process
Age
From **15 years** old to **17 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
Randomization method In order to select a school in this study, a specific number is assigned to each school (with secondary education) and then, the desired school is chosen through drawing. Furthermore, a certain number is assigned to each member of the study sample for random selection of examination and control groups, and then, drawing is once again used to allocate each number to the control or study groups. The rand function of Excel software is utilized for random allocation.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Not noted

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Semnan branch
Street address
University town, Semnan
City
Semnan
Province
Semnan
Postal code
983513137111
Approval date
2022-07-19, 1401/04/28
Ethics committee reference number
IR.IAU.SEMNAN.REC.1401.023

Health conditions studied

1

Description of health condition studied
Rumination
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Anxiety
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Depression
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Rumination
Timepoint
Repetitive negative thoughts (Rumination) are measured in the experimental group once before the intervention and once one month after the intervention. No measurement is carried out in the control group.
Method of measurement
Questionnaire of repetitive negative thoughts.

Secondary outcomes

1

Description
Anxiety
Timepoint
Anxiety is measured in the experimental group once before the intervention and once one month after the intervention. No measurement is done in the control group.
Method of measurement
Questionnaire of OASIS.

2

Description
Depression
Timepoint
Depression in the experimental group is measured once before the intervention and once one month after the intervention. No measurement is done regarding the control group.
Method of measurement
Questionnaire of ODSIS.

Intervention groups

1

Description
The Intervention with cognitive therapy based on mindfulness is implemented on the experimental group in the counseling center for 10 sessions of 60 minutes (one session per week). Here is a brief description of the topics of each session: first session: getting to know one another, second session: moving from living passively, to living consciously and with a conscious decision, third session: moving from connecting with experiences through thinking, to feeling those experiences directly, fourth session: Passing from being present in the past and future to being fully present in the moment. Fifth session: Moving from avoiding, escaping, or getting rid of unpleasant experiences to a desire to touch all experiences. Sixth session: passing from depending on the existence of differences, to accepting everything as it is. Seventh session: Moving from considering thoughts as reality to considering them as mental events that may not correspond to reality. Eighth session: Moving from being strict with oneself to taking care of oneself with kindness and compassion. Ninth session: Planning for a Mindful Future. Tenth session: reviewing previous sessions and summarizing.
Category
N/A

2

Description
Control group: No intervention is performed for the control group and it will undergo post-test.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khadijah Kobra High School, Taybad
Full name of responsible person
Maryam Safarzadeh
Street address
Taamin-e Ejtemaei Street, Imam Hossein town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
MOhammad Karim Sohrabi
Street address
Islamic Azad University, University campus
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Semnan
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Phone
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Fax
+98 23 3365 4036
Email
321@semnaniau.ac.ir
Web page address
https://semnan.iau.ir
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
Neda BazrAfshan
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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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
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
Information about the principal results can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
People working in medical and academic institutions.
Under which criteria data/document could be used
Allowed for therapeutic and research use.
From where data/document is obtainable
Refer to Islamic Azad University, Semnan branch to use data.
What processes are involved for a request to access data/document

After submitting an application to the president of the University of Medical Sciences and obtaining permission.

Comments