

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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

Country

Iran (Islamic Republic of)

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+98 51 5453 0893

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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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Razavi Khorasan

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989591869443

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nedabazrafshan647@gmail.com

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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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