

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effectiveness of Adolescent-Centered Mindfulness Treatment and Emotion Regulation Strategies Training on High-Risk Behaviors, Mind Wandering and Symptoms of Depressed Adolescents

Protocol summary

Study aim

This research is conducted with the aim of comparing the effectiveness of adolescent-oriented mindfulness therapy and teaching emotion regulation strategies on high-risk behaviors, mind wandering, and adolescent depression.

Design

Randomised clinical trial has a control group, double-blind, on 45 depressed teenagers.

Settings and conduct

A semi-experimental research has been conducted on depressed teenage girls in Isfahan city in 1400. double-blind (experimental group and control group).

Participants/Inclusion and exclusion criteria

Entry requirements: 1. Age range of 13-17 years, 2. Having literacy, 3. Not suffering from acute or chronic mental disorders in the past week (confirmed by a psychiatrist or clinical psychologist), 4. Not using From concurrent psychological treatments, 5. not taking psychiatric drugs for the past 3 months (by asking the clients) and 6. not suffering from physical diseases (diagnosed by a doctor and acknowledged by the client) that prevent them from participating in the plan be research Non-entry conditions: 1. Unwillingness to continue research; 2. Failure to do the assignments given in the sessions and 3. Absence of more than 2 sessions during the treatment.

Intervention groups

The first experimental group underwent eight weekly sessions of adolescent-oriented mindfulness. The second experimental group underwent eight training sessions on emotion regulation strategies. and the control group that did not receive any intervention.

Main outcome variables

Effective exposure of adolescents to dysfunctional people, events and attitudes Enhancing non-judgmental attention to a specific event in the present

General information

Reason for update

Acronym

MBT

IRCT registration information

IRCT registration number: **IRCT20230116057137N2**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

Registrant information

Name

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Name of organization / entity

Safahan Institute of Higher Education

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Adolescent-Centered Mindfulness Treatment and Emotion Regulation Strategies Training on High-Risk Behaviors, Mind Wandering and Symptoms of Depressed Adolescents

Public title

Effect of Adolescent-Centered Mindfulness Treatment and Emotion Regulation on High-Risk Behaviors, Mind Wandering and Symptoms of Depression.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Age range 13-17 years 2. Being able to read and write 3. Not suffering from acute or chronic mental disorders during the past week (confirmed by a psychiatrist or clinical psychologist) 4. Not using simultaneous psychological treatments 5. Not taking psychiatric drugs for the past 3 months (by asking clients) 6. Not suffering from physical diseases (diagnosed by a doctor and acknowledged by the client)

Exclusion criteria:

Being over 18 years old Suffering from physical and movement diseases Being illiterate or illiterate Suffering from chronic psychological diseases People undergoing psychological treatment. People who are taking psychiatric medication.

Age

From **12 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method: simple random draw Randomization Unit: Individual Randomization tool: Lottery The numbers 1-60 are randomly distributed among 60 subjects, then we put the numbers 1-60 in the box and the first 15 numbers out of the box are in the first test group and the second 15 numbers are in the second test group and the remaining people in the group are under control.

Blinding (investigator's opinion)

Single blinded

Blinding description

Double-blind means that the people in the sample group did not know whether they were in the experimental group or the control group. Therefore, explaining the objectives of the research only for the experimental group and ignorance of the selection in the two groups was the blinding method of the present study, considering that after the work was completed, the

treatment was also applied to the control group.

Placebo

Not used

Assignment

Other

Other design features

A factorial trial with a design provides separate assessment of the effects of more than one treatment.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University

Street address

No. 8, Afshin Alley, Khaghani Street

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Province

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Postal code

8175857174

Approval date

2022-12-05, 1401/09/14

Ethics committee reference number

IR.UI.REC.1401.098

Health conditions studied**1****Description of health condition studied**

High-Risk Behaviors, Mind Wandering, Depression

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

People who, in addition to having files in counseling centers with a diagnosis of depression, scored more than 20 in Beck's depression questionnaire.

Timepoint

Investigating depression at the beginning of the study, 60 and 45 days after the intervention

Method of measurement

Beck depression questionnaire

Secondary outcomes**1****Description**

Reducing High_Risk behaviors

Timepoint

At the beginning of the study and 60 and 45 days after the intervention

Method of measurement

Questionnaire of risky behaviors

2

Description

Reducing mind wandering

Timepoint

At the beginning of the study and 60 and 45 days after the intervention

Method of measurement

Wandering Mind Scale

Intervention groups

1

Description

Intervention group: First, the first experimental group underwent eight weekly sessions of 60 minutes of adolescent-oriented mindfulness using the manual for teaching mindfulness skills to children and adolescents by Burdick .

Category

Treatment - Other

2

Description

Intervention group: Second, the second experimental group underwent eight weekly sessions of 60 minutes of emotion regulation strategies training using the book Emotion Regulation Strategies by Grass.

Category

Treatment - Other

3

Description

Control group: They did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Safahan Counseling Center

Full name of responsible person

Raziyeh Izadi

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Safahan Institute of Higher Education

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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

Safahan Institute of Higher Education

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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Consultant
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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

There is no further information.

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