Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Emotion-Focused Therapy and Adolescent- Centered Mindfulness Training on Cognitive Fusion and Self-Concept Of Girls with High Risk Behaviors tendencies

Protocol summary

Study aim
Determining the Effectiveness of and Comparing Emotion-Focused Therapy and Adolescent-Centered Mindfulness Training on Cognitive Fusion and Self-Concept in Adolescent Girls Prone to Risky Behaviors

Design
A randomized, single-blind, parallel-group, controlled clinical trial conducted on 60 participants.

Settings and conduct
Research setting: selected girls' secondary schools Collection of baseline data within the school environment. The students were unaware of the implementation procedure. Members of the two groups—the intervention group and the control group—came from three different schools and did not know one another.

Participants/Inclusion and exclusion criteria
Inclusion criteria : being female; enrollment in an upper secondary school during the academic year in which the study was conducted; engagement in one or more high-risk behaviors; no prior participation in similar workshops or educational classes; absence of psychiatric disorders or concurrent therapeutic interventions; provision of informed consent to participate; and achieving a score equal to or greater than the cutoff score of 95 on the Iranian Adolescent Risk-Taking Questionnaire—used as the primary criterion for identifying eligible participants. It should be noted that meeting this criterion indicates that the participant exhibits a significant level of propensity toward high-risk behaviors, as assessed by the screening instrument. Exclusion criteria: Inability to attend the 8 educational sessions or absence from more than two sessions; dissatisfaction with the sessions at any stage of the study; failure to cooperate with therapeutic assignments; and the use of psychiatric medications or receipt of concurrent therapeutic interventions.

Intervention groups
Emotion-Focused Therapy Intervention Group
Adolescent-Focused Mindfulness Training Intervention Group

Main outcome variables
Cognitive Fusion Self-Concept

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261018071474N1**
Registration date: **2026-11-02, 1405/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-02, 1405/08/11**
Update count: **0**

Registration date
2026-11-02, 1405/08/11

Registrant information

Name
mahdiyeh Pakdaman

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-26, 1405/08/04

Expected recruitment end date

2026-11-25, 1405/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Emotion-Focused Therapy and Adolescent- Centered Mindfulness Training on Cognitive Fusion and Self-Concept Of Girls with High Risk Behaviors tendencies

Public title

Comparing the Effectiveness of Emotion-Focused Therapy and Adolescent- Centered Mindfulness Training on Cognitive Fusion and Self-Concept Of Girls with High Risk Behaviors tendencies

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

being female being enrolled in upper secondary school during the academic year in which the research was conducted, engaging in at least one (or more) high-risk behavior(s) provide consent and score at or above the cutoff point of 95 on the Iranian Adolescent Risk-Taking Questionnaire having no psychiatric disorders or concurrent therapeutic interventions. participants were required to —a primary criterion for identifying eligible candidates Consent to participate in the research

Exclusion criteria:

I use of psychiatric medications receipt of concurrent therapeutic interventions. Unwillingness to participate in research

Age

From **14 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Step 1: To select girls' upper secondary schools, three schools are chosen using a non-random, purposive sampling method. Phase Two: Screening and identification of eligible students (those scoring at or above the cut-off score of 95 on the Iranian Adolescent Risk-Taking Questionnaire) in selected schools. A total of 60 eligible students will be selected from 3 designated schools (20 students from each school). Step 3: Following the traditional lottery method, each of the selected schools is assigned a number. The selection of 60 eligible students—to be placed into the experimental and control groups—is carried out by randomly drawing a number from a container.

Blinding (investigator's opinion)

Single blinded

Blinding description

This task was carried out by the researcher and the instructor of the two interventions. The participants in this study, who were students, were unaware of the details. Each of the group intervention sessions was conducted in two separate schools at different times by a single therapist (trained in the research interventions), and the members of the two experimental groups did not know one another.Members of the control group were also selected from a separate school. To minimize the risk of cross-contamination between the interventions, the two treatment groups were organized separately, and the sessions for each intervention were conducted in independent groups. Throughout the implementation of the interventions, members of each group remained unaware of the content of the other group’s sessions; furthermore, they were instructed not to share the session content or the activities performed with students outside their own group. Additionally, the sessions for the two interventions were held at different times, and participants were assigned to their respective groups prior to the commencement of the intervention. Given that the participants were drawn from the same school community, the potential for interaction and the exchange of information among students—a possible source of contamination—was taken into account; this risk was mitigated as much as possible by conducting the sessions separately and emphasizing the confidentiality of the session content.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Islamic Azad University, Ardabil Branch

Street address

Basij Square

City

Ardabil

Province

Ardabil

Postal code

: ۵۶۱۵۷۳۱۵۶۷

Approval date

2025-10-06, 1404/07/14

Ethics committee reference number

IR.IAU.ARDABIL.REC.1404.235

Health conditions studied

1

Description of health condition studied
High Risk Behaviors tendencies
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cognitive Fusion
Timepoint
Pre-test, post-test, 3-month follow-up
Method of measurement
Gillanders Cognitive Fusion Test

2

Description
Self-Concept
Timepoint
Pre-test, post-test, 3-month follow-up
Method of measurement
Beck Self-Concept Test

Secondary outcomes

empty

Intervention groups

1

Description
Emotion-Focused Therapy will be conducted in a group format over eight weekly, 60-minute sessions. The protocol is based on the book *Emotion-Focused Therapy in Practice* (Elliott & Greenberg, 2021; translated by Ramezani et al., 2024).
Category
Treatment - Other

2

Description
Adolescent-focused mindfulness training will be conducted in a group format over eight 60-minute weekly sessions. The protocol is based on the *Mindfulness Skills Training Manual for Children and Adolescents* (Burdick, 2014; translated by Monshi et al., 2021).
Category
Treatment - Other

3

Description
Control group: Without intervention and on the waiting list
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaffari School
Full name of responsible person
Mahdiyeh Pakdaman
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy for Research and Technology, Islamic Azad University, Ardabil Branch

Full name of responsible person
Dr Ali Mansuri

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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
Deputy for Research and Technology, Islamic Azad University, Ardabil Branch

Proportion provided by this source
10

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
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Position
Psychologist

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participants' data and scores will be recorded in an Excel file and subjected to statistical analysis; the results of this analysis will be published in the doctoral dissertation and as a research article.

When the data will become available and for how long

After the work is finished

To whom data/document is available

Principal Investigator, Supervisors, and Advisors, Supervisors, and Advisors

Under which criteria data/document could be used

Publishing research results

From where data/document is obtainable

Principal Investigator Mahdiyeh Pakdaman Contact Number 00989113363596

What processes are involved for a request to access data/document

Contacting the principal researcher to receive guidance on obtaining data and data analysis results, within a maximum period of 2 months.

Comments