

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of cognitive behavioral therapy on feelings of shame and guilt, impulsive behaviors, and difficulty in emotion regulation in adolescents with high-risk behaviors.

Protocol summary

Study aim

Determining the effectiveness of cognitive behavioral therapy on feelings of shame and guilt, impulsive behaviors, and difficulty in emotion regulation

Design

The clinical trial will be a controlled, parallel-group, single-blind, randomized, controlled trial on 40 adolescents. It will be conducted using R software for block randomization (block size 4).

Settings and conduct

This quasi-experimental study will be conducted on 40 adolescents with high-risk behaviors in Ahvaz city, who will be randomly assigned to two groups of 20 (experimental and control).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent, interest and willingness of individuals to participate in the research and their parents, ability to read, write and complete the informed consent form, age range of 14 to 17 years, symptoms of high-risk behaviors by the participant and subsequently obtaining a score higher than the average of this scale, adolescents with high-risk behaviors in Ahvaz city. Major exclusion criteria: Simultaneous participation in other training and treatments, having chronic physical disorders and inability to follow up the subject.

Intervention groups

The intervention group will receive a structured cognitive-behavioral therapy (CBT) program consisting of 12 weekly 60-minute sessions. The intervention will focus on emotion regulation training, cognitive restructuring of shame- and guilt-related beliefs, and impulse control skills training, and will be delivered by trained therapists in a clinic or school setting. The control group will receive usual psychological services (Treatment as Usual), consisting of unstructured counseling and periodic monitoring without the CBT protocol.

Main outcome variables

Feelings of shame, guilt, impulsive behaviors, difficulty regulating emotions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250703066357N1**

Registration date: **2025-08-27, 1404/06/05**

Registration timing: **prospective**

Last update: **2025-08-27, 1404/06/05**

Update count: **0**

Registration date

2025-08-27, 1404/06/05

Registrant information

Name

nilofar raessi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-20, 1404/06/29

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral therapy on feelings of shame and guilt, impulsive behaviors, and difficulty in emotion regulation in adolescents with high-risk behaviors.

Public title

The effectiveness of cognitive behavioral therapy on feelings of shame and guilt, impulsive behaviors, and difficulty in emotion regulation.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent, interest and willingness of individuals to participate in the research and their parents Ability to read, write, and complete an informed consent form Age range 14 to 17 years The participant exhibits signs of high-risk behaviors and subsequently scores higher than the average on this scale. Adolescents with high-risk behaviors in Ahvaz city

Exclusion criteria:

Simultaneous participation in other training and treatments Having chronic physical disorders and not being able to follow up with the subject during the pre-test-post-test stages

Age

From **14 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In the future study, stratified randomization will be used. The unit of randomization will be the individual, and participants will be divided into strata based on key variables (such as gender and severity of risky behavior). Within each stratum, participants will be assigned to experimental and control groups using block randomization with a block size of 4. The random sequence will be generated using specialized software (such as R or SPSS) and placed in sealed envelopes or an online concealment system to reduce bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor who measures the primary and secondary outcomes (shame, guilt questionnaires, etc.) will be kept unaware of each participant's allocation to the

intervention or control group. The allocation of participants to groups will be done by an independent collaborator who is not involved in the assessment or intervention process, and the list will be kept confidential. The raw data will be provided to the analyst for statistical analysis, with non-specific codes (e.g. Group 1 and Group 2). The true identity of the groups (experimental or control) will only be revealed to the analyst after the primary final analyses have been completed. Due to the active nature of the psychosocial intervention, participants and therapists will be aware of their group and therefore will not be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Islamic Azad University, Ahvaz Branch

Street address

Islamic Azad University Ahvaz Branch, Farhangshahr, Golestan Highway

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Ahvaz

Province

Khuzestan

Postal code

3733361349

Approval date

2025-08-16, 1404/05/25

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.344

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

Risky behaviors in adolescents

ICD-10 code

Z72.9

ICD-10 code description

Problem related to lifestyle, unspecified

Primary outcomes**1****Description**

feeling ashamed

Timepoint

Outcome variables will be measured at three time points: pre-intervention, end of intervention, and 3-month follow-up

Method of measurement

Shame and Guilt Questionnaire by Cohen et al. (2011)

Secondary outcomes

1

Description

Risky behaviors

Timepoint

Risky behaviors will be measured at three time points: before the intervention, three months later, and at the end of the intervention and 3-month follow-up

Method of measurement

High-Risk Behavior Scale (YRBS)

2

Description

Cognitive regulation of emotion

Timepoint

Cognitive emotion regulation will be measured at three time points: before the intervention, at the end of the intervention, and at the 3-month follow-up

Method of measurement

Cognitive Emotion Regulation Questionnaire (CERQ):

Intervention groups

1

Description

Intervention group: The intervention will consist of 12 weekly sessions of CBT for adolescents with high-risk behaviors in Ahvaz city, focusing on rebuilding shame and guilt beliefs, training in emotion regulation, and impulse control. The experimental group will receive this intervention, while the control group will only receive routine monitoring. Outcomes will be assessed in three stages: pre-test, post-test, and 3-month follow-up. All sessions will be delivered by trained therapists in selected centers in Ahvaz.

Category

N/A

2

Description

Control group: The control group in this study will not receive any active intervention and will only be monitored by the counseling centers as usual (such as general support sessions without a structured CBT protocol). After the study ends, this group will be given the opportunity to receive the CBT intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ahvaz Unit

Full name of responsible person

Shams Sobhani Joo

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Sponsors / Funding sources

1

Sponsor

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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

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

Shams Sobhani Joo

Position

Associate professor

Latest degree

Ph.D.

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)

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable