Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Development and Preliminary Evaluation of a Lived-Experience-Informed Protocol for Reducing the Severity of Suicidal Ideation in Adolescents

Protocol summary

Study aim

Elucidating the process of suicidal ideation formation in adolescents, developing a prevention protocol, and evaluating its effectiveness. Developing a prevention protocol based on qualitative findings and research evidence. Assessing and validating the protocol's content validity through expert review. Evaluating the effectiveness of the protocol in reducing suicidal ideation among adolescents.

Design

A single-blind, randomized controlled trial was conducted with 30 participants. G*Power software was utilized.

Settings and conduct

The protocol was evaluated using a quasi-experimental pretest-posttest design with a control group, involving 30 eligible adolescents visiting comprehensive health centers in Abhar County who were randomly assigned to two groups across two different centers.

Participants/Inclusion and exclusion criteria

Aged 12–18 years. Current or past experience of suicidal thoughts or attempts. Adequate cognitive and communication abilities for an interview. Ability to articulate experiences and feelings related to the topic. Obtaining consent from the adolescent and their parent or guardian.

Intervention groups

A total of 30 participants (15 per group)—meeting the minimum acceptable sample size—were included; the experimental group received the prevention protocol over eight sessions. Subsequently, changes in the research variables were examined by comparing the pre-test and post-test results of the two groups.

Main outcome variables

Suicidal thoughts, self-harming behavior: Suicidal ideation was considered the primary outcome, while emotion regulation difficulties, hopelessness, and perceived social support were viewed as constructs associated with the process of the formation and persistence of suicidal ideation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261001071250N1**
Registration date: **2026-10-05, 1405/07/13**
Registration timing: **retrospective**

Last update: **2026-10-05, 1405/07/13**
Update count: **0**

Registration date

2026-10-05, 1405/07/13

Registrant information

Name

Fatemeh SHakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

2026-07-01, 1405/04/10

Actual recruitment end date

2026-08-01, 1405/05/10

Trial completion date

2026-09-01, 1405/06/10

Scientific title

Development and Preliminary Evaluation of a Lived-Experience-Informed Protocol for Reducing the Severity of Suicidal Ideation in Adolescents

Public title

Development and evaluation of a protocol based on the experiences of adolescents who have attempted suicide.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 12 and 18 years Current or past experience of suicidal thoughts or actions Cognitive and communication abilities suitable for an interview Ability to articulate experiences and feelings related to the topic Consent from the adolescent and their parent or guardian to participate in the research

Exclusion criteria:

Unwillingness to continue participation at any stage Excessive absence from intervention sessions Concurrent receipt of similar psychological intervention during the course of the research Occurrence of circumstances rendering the individual's continued participation unsuitable

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Controlled After identifying eligible individuals, each participant was assigned a unique code. Then, using a table of random numbers, the individuals were evenly assigned to two groups—an experimental group (15 participants) and a control group (15 participants)—to ensure the groups were as homogeneous as possible regarding background variables such as age, gender, and the severity of suicidal thoughts.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were unaware of the existence of two groups, and the two groups were completely separate.

Placebo

Not used

Assignment

Other

Other design features

Randomized controlled trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Psychology, University of Tehran

Street address

Shahid Chamran Highway, Jalal-e-Al-Ahmad Street, opposite Kuye Nasr, Dr. Kardan Street

City

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Province

Tehran

Postal code

1445983861

Approval date

2026-04-07, 1405/01/18

Ethics committee reference number

IR.PSYEDU.TU.REC.1405.034

Health conditions studied

1

Description of health condition studied

Suicidal thoughts or suicide attempts

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of suicidal ideation, hopelessness, emotion regulation difficulties, and perceived social support.

Timepoint

The adjusted mean BSSI score was 12.32 for the experimental group and 23.41 for the control group; thus, after controlling for pre-test scores, an 11.09-point difference was observed between the two groups.

Method of measurement

Multivariate analysis of covariance (MANCOVA) was used to select eligible participants—based on scores exceeding the cut-off points on the BSSI, the Beck Scale for Suicide Ideation, the Beck Hopelessness Scale, the Difficulties in Emotion Regulation Scale, and the Multidimensional Scale of Perceived Social Support—and to examine changes following the intervention.

Secondary outcomes

1

Description

BHS، DERS، MSPSS

Timepoint
Two months for the qualitative phase, two months for protocol development, and two months for evaluation and implementation.

Method of measurement
Severity of suicidal ideation: The Beck Scale for Suicide Ideation (BSSI) consists of 19 core items, each scored on a three-point scale ranging from zero to two. The total score ranges from 0 to 38. The Emotion Regulation Difficulty Scale consists of 36 items and six main components. The MSPSS scale consists of 12 items and three main sources of social support.؛ To assess the level of hopelessness and negative attitudes toward the future among participants, the 20-item Beck Hopelessness Scale was used, which employs a dichotomous (true/false) response format.

Intervention groups

1

Description
Intervention group: Adolescents with suicidal thoughts in the intervention group received training (based on a prevention protocol developed by the researcher), and the changes were examined.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Abhar Health Network Comprehensive Health Center

Full name of responsible person
Fatemeh Shakeri

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Dr. Beheshti Street – Shahid Moradi Alley, Health Worker Training Center (next to the Central Laboratory)

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Sponsors / Funding sources

1

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Grant name
اطلاعی ندارم

Grant code / Reference number
02323

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
University of Tehran

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
University of Zanjan

Full name of responsible person
فاطمه شاکری

Position
Instructor

Latest degree
Master

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
Undecided - It is not yet known if there will be a plan to make this available

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