

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

The effect of intervention family empowerment on the severity of suicidal thoughts and recurrence of attempted suicide in acting teenagers

Protocol summary

Study aim

Determining the effect of family empowerment intervention on the intensity of suicidal thoughts and recurrence of suicidal attempts in adolescents.

Design

The clinical trial has a control group, is randomized on 80 patients, and the block method is used for randomization.

Settings and conduct

The research units are 80 family members of adolescents who attempted suicide and were hospitalized in the pediatric ward of Ibn Sina Hospital. They will be randomly assigned to two intervention and control groups. The intervention group will receive 5 45-minute sessions of empowerment in the field of suicide (severity and recurrence). Blinding will not be performed.

Participants/Inclusion and exclusion criteria

Adolescents inclusion criteria : At least one suicide attempt, Admission to Ibn Sina Hospital , Living with at least one family member permanently Adolescents Exclusion criteria: Severe mental disability Family inclusion criteria : No previous participation in empowerment and education courses Family Exclusion criteria :behavioral disorders

Intervention groups

The intervention group consists of families of suicidal adolescents who will receive family empowerment interventions throughout the course. The control group consists of families of suicidal adolescents who will receive empowerment interventions at the end of the course.

Main outcome variables

Severity of suicidal ideation (score from the Beck Suicidal Ideation Questionnaire); Number of suicide attempt recurrences during the follow-up period; Time to first suicide attempt recurrence (in days or months); Rate of readmission to hospital or emergency room due to suicide attempt; Level of family cohesion, support, and functioning (score from the Family Empowerment

Questionnaire).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260512069371N1**

Registration date: **2026-06-09, 1405/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2026-06-09, 1405/03/19**

Update count: **0**

Registration date

2026-06-09, 1405/03/19

Registrant information

Name

mohaddesh hasanzadehmoghaddam

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-07-06, 1405/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intervention family empowerment on the severity of suicidal thoughts and recurrence of attempted suicide in acting teenagers

Public title

The effect of family empowerment on suicidal thoughts and recurrence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescents: 1-At least one suicide attempt 2-Admission to Ibn Sina Hospital 3-Living with at least one family member permanently 4-Residing in the city and not facing legal prosecution 5-Being literate family: 1- Be literate 2- Have not participated in previous empowerment and training courses 3- Do not have any DSM-5 disorders 4- Do not have any life-threatening or disabling physical disorders 5- Be over 18 years old and under 65 years old

Exclusion criteria:

Adolescents: Severe mental disability family: participating in empowerment and other training courses Behavioral disturbance, evidence of prior psychosis Participate in other empowerment and training courses Severe mental disability that impairs the ability to understand informed consent

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

"This study will use a block randomization method with variable block sizes (4 and 6). The randomization unit was the individual (each patient). Randomization will be stratified by gender (male/female) and disease severity (mild/moderate/severe). The randomization sequence will be determined using the website.sealedenvelope. For allocation concealment, opaque, sealed, and sequentially numbered envelopes will be used. The allocation sequence is hidden from the investigator. The envelopes will be opened by someone independent of the principal investigator. The quasi-randomization method was not used in this study."

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Kharazmi Complex, Faculty of Nursing

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Province

Razavi Khorasan

Postal code

9137913199

Approval date

2026-02-28, 1404/12/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1404.140

Health conditions studied

1

Description of health condition studied

suicide

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of suicidal ideation score based on the Beck Scale for Suicidal Ideation (BSSI), which has a minimum score of 0 and a maximum score of 38. A higher score indicates greater severity of suicidal ideation.

Timepoint

Both groups will receive the Beck Suicidality Scale (BSSI) questionnaire, demographic information questionnaire, and Family Empowerment Scale (FES) in the pre-test phase, and the Beck Suicidality Scale and Family Empowerment Scale in the post-test phase (one month after training).

Method of measurement

Beck Suicidal Thought Questionnaire and Family Empowerment Questionnaire

2

Description

Number of suicide attempts during the two-month follow-up period (number of times the adolescent attempts

suicide again that requires hospitalization or emergency room visit).

Timepoint

After a two-month period of family empowerment, we will check for repeated suicide attempts by calling the family and reviewing the hospital's list.

Method of measurement

Using a phone call to family

Secondary outcomes

empty

Intervention groups

1

Description

After the research units of the intervention group were determined, the researcher made the necessary coordination with the respected supervisor to hold the date and time of the meetings and informed them on the Yes channel. And by creating a survey to check the presence of caregivers the night before, the date and time of the meetings were finalized. Family empowerment sessions were held every other day for two weeks, with 3 45-minute sessions each week in the classroom of the pediatric ward of Ibn Sina Teaching Hospital. During the empowerment sessions, exercises were included in some sessions that the research units were required to do, and the assignments were explained in person in the next session, and the caregivers were discussed about the assignment and its feedback. It should be noted that the content of the sessions was summarized in the Yes channel related to the group after the end of each session. Content of the sessions: Session 1: Coping with the phenomenon of suicide by caregivers, self-care b) What should I tell people? Session 2: Safety planning for suicidal concerns Session 3: Crisis prevention planning Session 4: Behavior modification Session 5: Review and summary of the material.

Category

Behavior

2

Description

Control group: Control group: After the research units were identified, training related to medication use and side effects was provided to the group. At the end of the period, empowerment training will be provided to the family.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Psychiatric Hospital

Full name of responsible person

Fatemeh Rajab Dizavandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Rajab Dizavandi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information and results will be provided anonymously.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Submit a written request to the principal investigator along with a formal letter of introduction and research proposal approved by the ethics committee. Permitted analyses include secondary analyses related to valid scientific purposes. Non-commercial use and attribution of the original source are required. Data will be provided in an anonymized form only. Requests will be reviewed by the research team and, if approved, will be delivered after signing a data confidentiality agreement.

From where data/document is obtainable

They can first email the corresponding author, Dr. Fatemeh Rajab Dizavandi, or the student, Mohaddeseh Hassanzadeh. Corresponding author email: rajabf2020@gmail.com Student email: mohaddesehhasanzadeh92@gmail.com

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

By sending an email to the responsible author or the relevant student, the file and data information will be received in less than a week, depending on the country's

conditions.

Comments