Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effectiveness of the strategic suicide prevention program based on cognitive therapy and improving life skills in adolescents

Protocol summary

Study aim
Determining the effectiveness of the strategic suicide prevention program based on cognitive therapy and improving life skills in teenagers of Qazvin province

Design
A controlled clinical trial with parallel groups, no blinding, randomized, phase 2 will be conducted on 36 teenagers. Using the appropriate formula the number of sample size was 14 people for each group, and with the probability of dropping 25% of the studied people in both groups, 36 people were considered. Randomization.com will be used for randomization.

Settings and conduct
This study will be conducted in selected health centers of Qazvin province. Before and after receiving psychological interventions, they will be examined for the presence of suicidal thoughts.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age, ability to communicate, accessibility, absence of serious mental or physical illnesses

Intervention groups
Implementation of cognitive therapy and life skills training Approach based on cognitive therapy along with conflict resolution between parents and children. The first session is to assess the level of suicide risk, to carry out a security plan for the individual. The second session of cognitive payment concept is done. The root of the client's issues and problems can be found. The third and fourth sessions are cognitive, emotional, and behavioral adaptive strategies for the client. Increasing the reasons for living and improving family relationships will be done in the fifth and sixth session on the limit of parent-child conflict.

Main outcome variables
Reducing the amount of suicidal thoughts; Increasing distress tolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240804062633N1**
Registration date: **2024-12-10, 1403/09/20**
Registration timing: **prospective**

Last update: **2024-12-10, 1403/09/20**
Update count: **0**

Registration date
2024-12-10, 1403/09/20

Registrant information

Name
Zahra Hosseinkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3336 8124

Email address
zhosseinkhani122@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-18, 1403/09/28

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of the strategic suicide prevention program based on cognitive therapy and improving life skills in adolescents

Public title
Investigating the effectiveness of the strategic suicide prevention program based on cognitive therapy and improving life skills in adolescents

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age greater than and equal to 13 years and less than 18 years Ability to communicate the patient or family with the questioner Living in Qazvin province Fixed mobile phone access

Exclusion criteria:
Having severe mental illnesses such as schizophrenia Suffering from severe physical diseases

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization phase will be done using balanced block randomization. Balanced block randomization means dividing participants into small blocks and then randomly assigning treatments within each block. This method is especially useful in clinical studies where the number of participants is limited. Blocks of 4 people will be used, each block will include 2 people in the treatment group and 2 people in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Bahonar Blvd

City
Qazvin

Province
Qazvin

Postal code
3419915315

Approval date
2024-10-02, 1403/07/11

Ethics committee reference number
IR.QUMS.REC.1403.244

Health conditions studied

1

Description of health condition studied
Suicide prevention

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Suicidal ideation score

Timepoint
At the beginning of the study and after the full implementation of cognitive therapy sessions and life skills training

Method of measurement
Suicidal ideation scale questionnaire

2

Description
Distress tolerance score

Timepoint
At the beginning of the study and after the full implementation of cognitive therapy sessions and life skills training

Method of measurement
Distress Tolerance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Approach based on cognitive therapy along with conflict resolution between parents and children. The first session is to assess the level of suicide risk, to carry out a security plan for the individual. The second session of the concept of cognitive payment is done. The root of the client's issues and problems can be found. The third and fourth sessions are cognitive,

emotional, and behavioral adaptive strategies for the client. Increasing the reasons for living and improving family relations will be done in the fifth and sixth session on the limit of parent-child conflict.

Category

Behavior

2

Description

Control group: 4 training sessions. First session: Psychologist assesses suicide risk level. Then the security plan for the client is checked. Then he takes a commitment from the person not to harm himself. In the second session of the security plan, the contents of the first session will be reviewed. Psychological education is given with the aim of reducing the suffering of the patient and all the assignments are given to the client with this aim. In the third session, the security plan is reviewed again, we have a review of the previous two sessions, and the false beliefs that exist in suicidal thoughts are discussed. In this session, problem solving training is given. In the fourth session, it is based on family education. It is discussed about family protective risk factors and suicide warning factors. Ways to deal with a person who wants to commit suicide.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Aref Comprehensive Health Service Center

Full name of responsible person

Ladan Mohammadizadeh

Street address

Aref Comprehensive Health Service Center, the beginning of Iranshahr street, Padgan street, Qazvin city

City

Qazvin

Province

Qazvin

Postal code

3413987314

Phone

+98 28 3332 1218

Email

phh@qums.ac.ir

2

Recruitment center

Name of recruitment center

Seraj Comprehensive Health Service Center

Full name of responsible person

Ladan Mohammadizadeh

Street address

Seraj Center, 2nd floor, Mohammadieh Specialized Clinic 2, opposite Fatemeh Zahra School, Golsar 1st Street, Mohammadieh City, Alborz County

City

Alborz

Province

Qazvin

Postal code

3491774316

Phone

+98 28 3257 3094

Email

phh@qums.ac.ir

3

Recruitment center

Name of recruitment center

Seraj Comprehensive Health Service Center

Full name of responsible person

Ladan Mohammadizadeh

Street address

Shohada Comprehensive Health Service Center (Seraj), Cinema St., 17 Shahrivar Square, Takestan City

City

Takestan

Province

Qazvin

Postal code

4381965787

Phone

+98 28 3524 7683

Email

phh@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mehdi Mirhashemi

Street address

Research and Technology Deputy, Mavedat Alley, First Alley , Beheshti Blvd

City

Qazvin

Province

Qazvin

Postal code

3415613911

Phone

+98 28 3333 7006

Email

researchdpt@qums.ac.ir

Web page address

https://qums.ac.ir/fa-IR/vcr.qums.ac/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
No
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Zahra Hosseinkhani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Research and Technology Deputy, Mavedat Alley, First Alley , Beheshti Blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Phone
+98 28 3333 7006
Email
zhosseinkhani122@gmail.com
Web page address
https://qums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zahra Hosseinkhani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Research and Technology Deputy, Mavedat Alley, First Alley , Beheshti Blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Phone
+98 26 3336 8124
Fax
Email
zhosseinkhani122@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zahra Hosseinkhani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Research and Technology Deputy, Mavedat Alley, First Alley , Beheshti Blvd
City
Qazvin
Province
Qazvin
Postal code
3415613911
Phone
+98 28 3333 7006
Email
zhosseinkhani122@gmail.com
Web page address
https://qums.ac.ir/

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

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