

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effect of life skills training on tendency toward high-risk behaviors in second grade high school students

Protocol summary

Study aim

Determining the effect of life skills training on high-risk behaviors

Design

Randomized clinical trial, double blind, random quadruple block, 100 students, Four groups (two intervention groups and two control groups)

Settings and conduct

Secondary Secondary Schools in Borujerd, Analyzer, coding of Questionnaires, Advisor, lack of data knowledge

Participants/Inclusion and exclusion criteria

second grade high school students Inclusion criteria • The sample cooperates with the study • Sample obtains at least fifty percent of the score • Samples reside in Boroujerd • Second grade high school students • The sample could participate in all sessions • No interference between sessions and classes of the sample Exit criteria - Already under stay on psychological counseling or psychiatry - Parental and sample discontent

Intervention groups

Education life skill to Intervention group(Self-knowledge skill, communication skill, Emotion Management Skill, Problem-solving skill, Decision-making skill, Critical thinking skill), At the end of the study, the training is given as a pamphlet to the control group

Main outcome variables

high risk behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038210N2**

Registration date: **2019-02-20, 1397/12/01**

Registration timing: **retrospective**

Last update: **2019-02-20, 1397/12/01**

Update count: **0**

Registration date

2019-02-20, 1397/12/01

Registrant information

Name

Elham Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3291 1047

Email address

eli885falalah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-04, 1397/10/14

Expected recruitment end date

2019-02-03, 1397/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of life skills training on tendency toward high-risk behaviors in second grade high school students

Public title

Effect of life skills training on tendency toward high-risk behaviors

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The sample cooperates with the study Sample obtains at least fifty percent of the score Sample reside in Boroujerd Second grade high school students No interference between sessions and classes of the sample The sample could participate in all sessions

Exclusion criteria:

Already under stay on psychological counseling or psychiatry Parental and sample discontent

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

startified randomized(Girls 'and boys' schools were considered as class), Systematic(Taking into account the city surface map), cluster(Schools were considered as clusters), randomization of quadrilateral block(Balance the number of samples in each group), coding of Questionnaires and failure to inform counsel & analyzer of codes

Blinding (investigator's opinion)

Double blinded

Blinding description

Analyzer: Data coding, Clinical watchful: Lack of data knowledge (Through clinical analyzer and clinical watchful have been blinded)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

khorrarnabad

City

khorrarnabad

Province

Lorestan

Postal code

6813833946

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.LUMS.REC.1397.151

Health conditions studied

1

Description of health condition studied

high risk behavior

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

high risk behavior

Timepoint

Before, immediately after and twenty days later

Method of measurement

Risk Assessment Questionnaire for Iranian Adolescents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:girl(Life skills training), 8 sessions 45-minute for 2 months and a follow-up meeting Twenty days after the last session, The sessions are arranged by clinical psychologists.

Category

Behavior

2

Description

Control group: girl(Lack of training)

Category

Behavior

3

Description

Intervention group: boy (Life skills training), 8 sessions 45-minute for 2 months and a follow-up meeting Twenty days after the last session, The sessions are arranged by clinical psychologists.

Category

Behavior

4

Description

Control group: boy(Lack of training)
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
High school
Full name of responsible person
ElhamFallh
Street address
Boroujerd
City
Boroujerd
Province
Lorestan
Postal code
6814967851
Phone
+98 66 3291 1047
Email
eli885falah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
dr.saki
Street address
khorramabad
City
khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3331 6303
Email
pr@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Elham Fallah
Position
Nursing student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Bahar street
City
Khoramabad
Province
Lorestan
Postal code
6814967851
Phone
+98 66 3291 1047
Fax
Email
eli885falah@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
ElhamFallah
Position
Nursingstudent
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Bahar street
City
khorramabad
Province
Lorestan
Postal code
6814967851
Phone
+66 32 911 047
Email
eli885fala@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

ElhamFallah

Position

Nursing student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

Bahar street

City

khorrabad

Province

Lorestan

Postal code

6814967851

Phone

+66 32 911 047

Email

eli885falah@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Title and more details about the data/document

After publishing the article in the magazine

When the data will become available and for how long

3 months after the publication of the article

To whom data/document is available

researchers

Under which criteria data/document could be used

Expression of the source of the data

From where data/document is obtainable

ElhamFallah eli885falah@gmail.com

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

Send email and state the reason for receiving the data

Comments