# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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, luck 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**
eli885falah@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**

khorramabad

**City**

khorramabad

**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

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Boroujerd

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

dr.saki

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**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

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## 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**