

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Providing and implementing Clinical trial of the prevention package for anxiety and depression in adolescent

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is prevention of anxiety and depressive disorders in adolescent population.  
**Design:** In a quasi-experimental study with control and experimental group, efficacy of anxiety and depression package in adolescent population will be performed.  
**Setting and conduct:** This study will be carried out in two phases. In the first phase, a prevention package for anxiety and depressive disorders is provided. In the second phase, the package is implemented among 80 samples, preliminary. **Participants:** Sampling will be selected from available student ages 11 - 18 years old, settled in Tehran. Participants are assigned randomly into two groups: experimental and control. **Intervention:** Prevention package is performed in group format, in 8 sessions. Control group is waiting for intervention after performing the study. **Variables:** Revised Children's Anxiety and Depression Scale is completed before, after, and after 3 months follow-up in two groups. Results are analyzed by co-variance method.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508274178N2**  
Registration date: **2016-12-07, 1395/09/17**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-07, 1395/09/17

##### Registrant information

###### Name

Abolfazl Mohammadi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5541 9151

###### Email address

amohammadi@stu.iums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Psychiatry and psychology research center of Tehran University of Medical Sciences

###### Expected recruitment start date

2016-04-20, 1395/02/01

###### Expected recruitment end date

2016-05-21, 1395/03/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Providing and implementing Clinical trial of the prevention package for anxiety and depression in adolescent

###### Public title

Prevention of Anxiety and Depression in Adolescent

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: age 11 to 18 years old; permission from parents of participants Exclusion criteria: having any cognitive or health problems that prevent students to participate to the program

###### Age

From **11 years** old to **18 years** old

###### Gender

Both

### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 80

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

Research Ethics Committee of Tehran university of Medical Sciences

##### Street address

6th floor, Central office of Tehran University of Medical Sciences, Ghods St. Keshavarz Blvd.

##### City

Tehran

##### Postal code

#### Approval date

2015-09-23, 1394/07/01

#### Ethics committee reference number

IR.TUMS.REC.1394.390

## Health conditions studied

### 1

#### Description of health condition studied

Symptoms of anxiety

#### ICD-10 code

F40

#### ICD-10 code description

Phobic anxiety disorders

### 2

#### Description of health condition studied

symptoms of Depression

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

## Primary outcomes

### 1

#### Description

Symptoms of anxiety

#### Timepoint

before and after intervention and after 3 month follow up

#### Method of measurement

Revised Children's Anxiety and Depression Scale (RCADS)

### 2

#### Description

Symptoms of depression

#### Timepoint

before and after intervention and after 3 month follow up

#### Method of measurement

Revised Children's Anxiety and Depression Scale (RCADS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Prevention package is performed in group format, in 8 sessions for experimental group.

#### Category

Prevention

### 2

#### Description

Control group is waiting for intervention after performing the study.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Helli High School

##### Full name of responsible person

Amir Teymouri

##### Street address

Zamanpour Alley, Mirdamadi St.

##### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Ms Karimi

**Street address**

Tehran University of Medical Sciences, Office of Vice-Chancellor for Research, floor 6, Ghods St., Keshavarz Blvd.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Abolfazl Mohammadi

**Position**

Assistant professor/ PhD

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*