

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)

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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

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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