

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effectiveness of the "Friends for Life" Program on Children's Anxiety and Depression

Protocol summary

Summary

Aim: This study evaluates the effectiveness of the "Friends for Life" cognitive behavioral program in reducing the symptoms of anxiety and depression in children. This study is a controlled trial with one pre intervention and two post intervention measurements. The study sample consists of 248 male students aged 10 years were screened using the Revised Children's Manifest Anxiety (RCMA) and the Children's Depression Inventory (CDI) in terms of mild to moderate symptoms of anxiety and depression. Of the subjects, 40 students met the inclusion criteria (RCMA>17, CDI=9 to 35, the absence of other psychiatric disorders require medical treatment) and they were randomized into intervention versus wait list comparison groups. The Strengths and Difficulties Questionnaire (SDQ), the Depression, Anxiety, Stress Scale (DASS) were filled out by parents of both groups. The children in the intervention group received the "Friends for Life" cognitive behavioral training program for eight 1 hour weekly sessions. Control group were placed on the waiting list. RCMA, CDI, DASS, SDQ were filled out again in both groups directly after, and 3 months after the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506215280N18**

Registration date: **2017-07-28, 1396/05/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-28, 1396/05/06

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences.

Expected recruitment start date

2013-10-07, 1392/07/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of the "Friends for Life" Program on Children's Anxiety and Depression

Public title

Evaluation of the Effectiveness of the "Friends for Life" Program on Children's Anxiety and Depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Revised Children's Manifest Anxiety >17; Children's Depression Inventory =9-35, the absence of other psychiatric disorders require medical

treatment. Exclusion criteria: Absence rate as 2 or more educational sessions; lack of fulfillment or defects of the questionnaires; experience of recent stressful event (past 6 months)

Age
From **9 years** old to **10 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Administration Center(Qoreishi Building), Daneshgah St., Mashhad, Iran.

City

Mashhad

Postal code

Approval date

2014-06-25, 1393/04/04

Ethics committee reference number

922855

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

2

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode

Primary outcomes

1

Description

Depression, Anxiety, Stress

Timepoint

Baseline. after the sessions and after 3 months.

Method of measurement

DASS: Depression, Anxiety, Stress

2

Description

Children's Depression

Timepoint

Baseline. after the sessions and after 3 months.

Method of measurement

Children's Depression Inventory

3

Description

Children's Anxiety

Timepoint

Baseline, after the sessions and after 3 months.

Method of measurement

RCMA: Revised Children's Manifest Anxiety

4

Description

Strengths and Difficulties

Timepoint

Baseline, after the sessions and after 3 months.

Method of measurement

SDQ: Strengths and Difficulties Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The children in the intervention group received the "Friends for Life" cognitive-behavioral training program for eight 1 hour weekly sessions.

Category

Treatment - Other

2

Description

The control group received a standard treatment and they were placed in waiting list.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn e Sina Hospital

Full name of responsible person

Street address

Ibn-e-Sina Hospital, Horeameli Avenue, Mashhad, Iran.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mahyar Mirheydari

Street address

Administration Center(Qoreishi Building), Daneshgah St., Mashhad, Iran.

City

Mashhad

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, Mashhad 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

Mashhad University of Medical sciences

Full name of responsible person

Dr Azam sadat Heydari

Position

specialist

Other areas of specialty/work

Street address

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Heydarias@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Psychiatry and Behavioral Sciences Research Center.

Full name of responsible person

Dr Fatemeh Moharrari

Position

specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Azam sadat Heydari

Position

specialist

Other areas of specialty/work

Street address

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Web page address

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