

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of training self-assertiveness skill on self-esteem and anxiety of adolescent with Bipolar I Disorder (BID) parent.

Protocol summary

Study aim

Effectiveness of self-assertiveness skill training on self-esteem and anxiety of adolescent with bipolar I disorder (BID) parent

Design

This research has two groups of control and intervention. The sample size is 30 for the intervention group and 30 for the control group. In this study, the study design is parallel. Type of trial is equivalence.

Settings and conduct

Self-assertiveness skill training will be performed on 30 adolescents with parent with type 1 bipolar disorder in a psychiatric department of Ebne sina hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: conscious consent to participate in the study by adolescent and healthy parents. the parent have diagnosed BID with a psychiatrist's approval. the age of adolescent between 11 to 18 years old. earn a score of at least 8 from the beck anxiety score. earn score 43 and less than cooper smith self-esteem. not married. not having drug addiction Non-Inclusion criteria: participate in other psychological programs during the intervention period history of psychiatric use or history of mental illness Unwillingness to participate in the study

Intervention groups

In the intervention group, the training of assertiveness skills was performed at 9 sessions, during 3 weeks, each session 90-minute, the meeting in one of the educational classes of the avicenna department of psychiatry and one hour before the appointment. In the control group, they do not receive training from the researcher and the routine process is done

Main outcome variables

Adolescent self-esteem, adolescent anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190521043660N1**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **retrospective**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

Registration date

2020-06-08, 1399/03/19

Registrant information

Name

Hasan Salimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3479 2409

Email address

salimihs961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

2019-07-01, 1398/04/10

Actual recruitment end date

2020-02-04, 1398/11/15

Trial completion date

2020-03-15, 1398/12/25

Scientific title

The effect of training self-assertiveness skill on self-esteem and anxiety of adolescent with Bipolar I Disorder (BID) parent.

Public title

The effect of training self-assertiveness skill on self-esteem and anxiety of adolescent.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The parents have diagnosed BID with a psychiatrist approval. The age of adolescent between 11 to 19 years old. Conscious consent to participate in the study by healthy adolescent and parent.

Exclusion criteria:

Participate in the other psychological programs to the during the intervention. History of used drug psychiatric. History of psychiatric disorder.

Age

From **11 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Non-random sampling (Inclusion of people in the study) will be available. then randomly assigned to two intervention and control groups in a balanced block design (4-person blocks). Thus, we have six models for preparing quadruple blocks (AABB, ABAB, ABBA, BBAA, BAAB, BABA). Here (intervention group = A) and (B= control group). Then, by drawing lots, the order of the blocks will be determined. Finally, random sampling of adolescents study will be based on the order of these blocks.

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**

Ethics Committee of University of Mashhad Medical Sciences

Street address

Mashhad, Ibn Sina St.-doctora Four-Way

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.032

Health conditions studied**1****Description of health condition studied**

Bipolar I disorder

ICD-10 code

F31.1

ICD-10 code description

Bipolar disorder, current episode manic without psychotic features

Primary outcomes**1****Description**

Self-Esteem

Timepoint

Self-esteem before the intervention, immediately after the intervention and one month after the end of the intervention

Method of measurement

Cooper Smith Self-Esteem Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, the assertiveness Training Program will be implementing the nine-point practical guideline. The training sessions will be 90 minutes. The intervention will be performing 3 times a week, the groups of 10 to 12 in the three groups and 21 days intervals between the groups. The sessions will be performed in the Psychiatry Department of the Ibn Sina Hospital, one hour before the appointment on Mondays, Wednesdays, and Fridays between 14 and 16 o'clock. To training assertiveness, The researchers should be use lectures and PowerPoint, discussions between small groups, role play, and homework. The class will be separated according to gender. The main content was determined by the educational intervention and considering the texts in life skills training books (life skills book of the Ministry of Health) and practical guidelines, Motabi and Kazem Zadeh. During the

intervention, the subjects actively participate in the curriculum and carry out teaching-learning activities with their participation.

Category

Lifestyle

2

Description

Control group: 30 Adolescent who will be randomly selected and will not receive any training, and completion of questionnaires will be conducted simultaneously with the intervention group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

IbnSina Hospital

Full name of responsible person

Fatemeh Moharri

Street address

Horr Ameli Boulevard

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Postal code

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghody

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hasan Salimi

Position

Master of Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hasan Salimi

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the outcome of the main message The ability to transfer the sharing

When the data will become available and for how long

One year after sharing results

To whom data/document is available

Our data will only be available to researchers working in academia.

Under which criteria data/document could be used

With the permission of Mashhad University of Medical Sciences, data will be available.

From where data/document is obtainable

Research Deputy of Mashhad University of Medical Sciences

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

You must apply for deputy from Mashhad University of Medical Sciences

Comments