

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Efficacy of Peer Group Support on resilience and Self-esteem in adolescents of parents with mood Disorder

#### Protocol summary

##### Study aim

Evaluating the effect of peer group counseling on adolescents with parents with mood disorders

##### Design

Randomized clinical trial using SPSS software randomly 50 people for the intervention group and 50 people for the control group.

##### Settings and conduct

Randomized clinical trial on children aged 12 to 18 years with patients with major depression and bipolar disorder performed at Kargarnejad Hospital in Kashan. The psychiatrist reviews the questionnaires and interviews without knowing the type of study group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adolescents aged 12 to 18 years, Parents who have been diagnosed mood disorder based on DSM 5 and a psychiatrist diagnosis Awareness that parents have a psychiatric illness. Written consent of parents or primary caregivers to attend group meetings, Willingness to attend the program, No psychiatric illness in adolescents. Exclusion criteria: Lack of consent Children do not want to participate or continue working in the group Age less than 12 and more than 18 years Adolescent psychiatric illness Absence of more than two sessions in a group

##### Intervention groups

The intervention group consisted of 50 people (including groups of 6 to 10 persons) and the control group of 50 persons. In the first group, people attend a 45- to 50-minute session each week for eight consecutive weeks. No intervention is performed on the control group (waiting list) Both groups answer the "Connor and Davidson Resilience" and "Rosenberg Self-Esteem" questionnaires at the beginning and end of 8 weeks.

##### Main outcome variables

Connor & Davidson test score (subscale of perception of individual competence, trust in individual instincts and tolerance of negative emotions, positive acceptance of change and safe relationships, control, spiritual effects)

Rosenberg self-esteem test score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210804052078N1**

Registration date: **2022-04-01, 1401/01/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-01, 1401/01/12**

Update count: **0**

##### Registration date

2022-04-01, 1401/01/12

##### Registrant information

##### Name

Tayebeh Panjehpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3264 6466

##### Email address

panjehpour-t@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-06, 1400/12/15

##### Expected recruitment end date

2022-04-21, 1401/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficacy of Peer Group Support on resilience and Self-esteem in adolescents of parents with mood Disorder

### Public title

Peer Group Support on resilience and Self-esteem in adolescents

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Adolescents aged 12 to 18 years Parents who have been diagnosed mood disorder based on DSM 5 Awareness that parents have a psychiatric illness Written consent of parents or primary caregivers to attend group Willingness to attend the program No psychiatric illness in adolescents

#### Exclusion criteria:

Lack of consent adolescents do not want to participate or continue participation in the group Age less than 12 and more than 18 years Adolescents with psychiatric illness Absence in more than two sessions

### Age

From **12 years** old to **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The study population will be first extracted from the children of 12 to 18 years old of parents with major depression or bipolar disorder who are undergoing outpatient treatment in Kargarnejad Clinic or Hospital and will be assigned a unique number. Using SPSS software, 50 people will be randomly selected for the intervention group and 50 people for the control group.

### 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 Kashan University of Medical Sciences

### Street address

Kashan University of Medical Sciences, Qotb Ravandi Blvd.

### City

kashan

### Province

Isfahan

### Postal code

73474-87159

### Approval date

2022-02-12, 1400/11/23

### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.177

## Health conditions studied

### 1

#### Description of health condition studied

Major Depressive Disorder

#### ICD-10 code

F32

#### ICD-10 code description

Major depressive disorder, single episode

### 2

#### Description of health condition studied

Bipolar Disorder

#### ICD-10 code

F31

#### ICD-10 code description

Bipolar disorder

## Primary outcomes

### 1

#### Description

Resilience

#### Timepoint

Weeks 0, 8

#### Method of measurement

Connor & Davidson Questionnaire

### 2

#### Description

Self esteem

#### Timepoint

Weeks 0, 8

#### Method of measurement

Rosenberg Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 50 children aged 12 to 18 years with patients with major depression and bipolar disorder, in groups of 6 to 10, for 8 consecutive weeks, one session of 45 to 50 minutes per week. The group is trained by the facilitator according to The Kids in Control program is guided by the concepts in Supportive Psychotherapy Learning Guide, Depression: Family Education Guide, Bipolar Disorder Education Guide, and pamphlets on the COPMI website. At the beginning of the sessions and at the end of the eighth week, the Conner and Davidson Resilience Questionnaire and Eisenberg Self-Esteem Questionnaire will be completed by the participants.

#### Category

Behavior

### 2

#### Description

Control group: Fifty children aged 12 to 18 years with patients with major depression and bipolar disorder are included in the study as a waiting list. In the beginning and eighth week, the Conner and Davidson Resilience Questionnaire and Eisenberg Self-Esteem Questionnaire are completed by the participants.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kargarnezhad Hospital ,Kashan

##### Full name of responsible person

Tayebeh Panjehpour

##### Street address

Blvd Ghotbe Ravandi

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715973446

##### Phone

+98 31 5554 9111

##### Email

Panjehpour-t@kaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Hamidreza Banafshe

#### Street address

Kashan University of Medical Sciences, Qotb Ravandi  
BLvd

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715988141

#### Phone

+98 31 5554 2999

#### Email

Banafshe57@hotmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kashan University of Medical Sciences

#### Proportion provided by this source

10

#### 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

Kashan University of Medical Sciences

##### Full name of responsible person

Tayebeh Panjehpour

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Psychiatrics

##### Street address

Kargarnezhad Hospital ,Qotb Ravandi Blvd.

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715973446

##### Phone

+98 31 5554 9111

##### Email

Panjehpour-t@kaums.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Fatemeh Assarian

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnezhad Hospital, Qotb Ravandi Blvd.

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Fatemeh Assarian

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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**Postal code**

8715973446

**Phone**

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**Email**

Fa-assar@yahoo.com

## **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**

Demographic characteristics of parents and adolescents, raw scores of Connor & Davidson test and Rosenberg test

**When the data will become available and for how long**

Access period starts one year after the results are published

**To whom data/document is available**

Researchers working for academic and scientific institutes

**Under which criteria data/document could be used**

For metaanalyses and systematic reviews and head to head studies

**From where data/document is obtainable**

Research Center of the Vice Chancellor for Research of Kashan University of Medical Sciences

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

Sending a request letter to the Vice Chancellor for Research of Kashan University of Medical Sciences approved by the supervisor attending of the project

**Comments**