

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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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

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Isfahan

Postal code

8715973446

Phone

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Assarian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Isfahan

Postal code

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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