Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of group education on self-care self-efficacy of adolescents with depressive disorder

Protocol summary

Study aim
Determining the effect of group education on the self-care self-efficacy of adolescents with depression referred to clinics affiliated to Shiraz University of medical sciences

Design
A clinical trial with a control group, parallel, with blinded data analysis, randomized by block permutation method on 96 patients.

Settings and conduct
This study is conducted on adolescents suffering from depression who refer to the clinics affiliated to Shiraz University of Medical Sciences, including Ibn Sina and Hafez hospitals, who are diagnosed and introduced by a psychiatrist. After completing the informed consent and doing pre-test the intervention starts. The number of people in the intervention group is 48, which are divided into 6 groups of 8 people. At the end of the last session, the post-test will be done by both intervention and control groups. This study is blinded by statistical data analyzer.

Participants/Inclusion and exclusion criteria
Entry criteria: Age 12-18 years The preparation and favorable physical and mental conditions of the patient to participate. Exit criteria: Refusal to continue participating in the study during the study. Presence of other accompanying psychiatric and cognitive disorders based on interview and doctor's diagnosis.

Intervention groups
10 sessions of group educational intervention for 90 minutes, 2 sessions per week will be presented to the intervention groups. The control group will receive routine treatment. The content includes lecture, discussion, exercises using methods such as telling stories, slides, photos and video clips.

Main outcome variables
The level of depression, which is measured by Beck's depression inventory, and the level of self-care self-efficacy in adolescent patients, which is measured by self-care self-efficacy inventory of Behzadi et al.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231126060197N1**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date
2023-12-07, 1402/09/16

Registrant information
Name
Arefeh Mohebbi Moghaddam
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-21, 1402/11/01
Expected recruitment end date
2024-03-20, 1403/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of group education on self-care self-efficacy of adolescents with depressive disorder

Public title
The effect of group education on depression
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 12-18 years old Willingness to participate in the study Parents' consent to adolescent participation in the study Preparation and favorable physical and mental conditions of the patient to participate in the intervention Having DSM-5 diagnostic criteria for depression Suffering from a depressive disorder based on the psychiatrist's diagnosis and the score obtained from the depression assessment questionnaire
Exclusion criteria:
Refusal to continue participating in the study during the study The occurrence of a crisis or an unforeseen event affecting the patient's mental state Inability to actively participate in the treatment process due to reasons such as slowness of thinking, slowness of speech, etc Presence of other accompanying psychiatric and cognitive disorders based on interview and doctor's diagnosis
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
People with conditions are randomly placed in two intervention and control groups. Random allocation method in this study is permutation block method in such a way that A represents the person who receives the intervention and B represents the person who does not receives the intervention. This method is implemented considering blocks of 4 so that the total number of possible permutations of four is equal to 6. (blocks of four included: BBAA, AABB, BABA, BAAB, ABBA, ABAB) The desired random list of 96 items, which includes 4 blocks of 6 items, is produced and the order of allocation of each of the participant samples in the intervention and control groups of the study is determined. The way to use the table of random numbers is to choose the starting point randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is done in a one-sided blind method by the person who did the data analysis and statistical analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Central department of Shiraz University of Medical Sciences, Zand St., Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-11-25, 1402/09/04
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.098

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

Primary outcomes

1

Description
self-care self-efficacy
Timepoint
Measurement of self-care self-efficacy at the beginning of the study (1st session) and at the end of the intervention (10th session)
Method of measurement
Behzadi et al.'s self-care self-efficacy of adolescents with mental disorders questionnaire, Beck depression inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: There are 48 patients in this group, which are divided into 6 groups of 8 people. Girls and boys are placed in separate groups. The people of each group are tried to be in the same age category. After completing the informed consent form, doing the pre-test and familiarization with study implementation method, 10 sessions of group educational intervention for 90 minutes will be provided to the intervention groups twice a week. The content of the educational intervention, in order to improve self-care self-efficacy, is based on the concepts obtained from Behzadi et al.'s research, which includes 4 main themes and each theme has 3 sub-themes: 1- Adaptive coping (emotional-oriented coping, problem-oriented coping and spiritual approach) 2- Social self-care (effective social interactions, acquiring social competence and management of high-risk behaviors) 3- Life adaptation to disease and treatment condition (healthy life style, management of complications caused by treatment and treatment adherence) 4- Health information seeking behaviors (searching for practical resources, assessing the quality of the information and how to use the information optimally)

Category
Lifestyle

2

Description
Control group:

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez hospital

Full name of responsible person
Arefeh Mohebbi Moghaddam

Street address
Hafez Medical Educational Center, District 1, Chamran Blvd., Shiraz

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2

Recruitment center

Name of recruitment center
Ebn Sina hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Shahrzad Yektatalab
Position
Associate professor, faculty member
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Informed consent form, non-identifiable data of participants, the study protocol and the report of clinical study
When the data will become available and for how long
The access period starts 6 months after the results are

published.

To whom data/document is available

The research team, researchers working in academic and scientific institutions as well as people working in industry.

Under which criteria data/document could be used

For the mentioned people with information of project manager.

From where data/document is obtainable

The main executive of project: Dr. Shahrzad Yektatalab
E-mail: yektash@sums.ac.ir Tel: +98 71 3647 4254

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

With the information and coordination of project manager.

Comments