

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of Group-Based Cognitive-Behavioral Therapy (CBT) in Psycho-Social Compatibility of Patients with Major Depression Disorder

Protocol summary

Study aim

Determining the Effect of Group-Based Cognitive-Behavioral Interventions in Social-Psychological Adjustment of Patients with Major Depressive Disorders

Design

First, all people who have the criteria for entry into the study complete the Bell Social Psycho-social Questionnaire. 104 patients with the criteria for study are selected. Patients will be treated with simple sampling in two groups: intervention and control. The intervention group participates in eight cognitive-behavioral training sessions. The control group will not receive any interventions during this period. After completing the intervention, both groups complete the Bell Compliance questionnaire. Finally, the data will be analyzed using statistical tests.

Settings and conduct

The study is a clinical trial with control group, pre-test and post-test. The place of the study is the Ebn-Sina Psychiatric hospital in Shiraz

Participants/Inclusion and exclusion criteria

Inclusion criteria (patients with non-psychotic depressive disorder with proper cognitive function) Exclusion criteria (depressed patients with psychotic symptoms and cognitive impairment)

Intervention groups

The Intervention group includes Cognitive-Behavioral education. Meetings are organized in a group manner. There will be two 90-minute sessions per week. The Control group does not receive Cognitive-Behavioral intervention. Receives pharmaceutical and public interventions

Main outcome variables

Improving social and psychological compatibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170808035579N1**

Registration date: **2018-01-14, 1396/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-14, 1396/10/24**

Update count: **0**

Registration date

2018-01-14, 1396/10/24

Registrant information

Name

Zakiye Ghelbash

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

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Recruitment status

Recruitment complete

Funding source

Government - Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-21, 1396/05/30

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Group-Based Cognitive-Behavioral Therapy (CBT) in Psycho-Social Compatibility of Patients with

Major Depression Disorder

Public title
Effect of Cognitive-Behavioral Therapy in Depression.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients With Major non-psychotic Depression Are aged 18 to 60 years old Reading and Writing skills
Exclusion criteria:
Patients in the active phase of psychosis Patients who have learning difficulties Destruction of the mental process Patients who are not Psychologically favorable for Treatment through Group Therapy

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random numbers, 50 people will be selected from all participants with the criteria for entering the study. All two-digit participant codes will be entered into the computer system of random numbers. Then start the first row or column. Two digit digits are smaller than the total number of participants. This process will continue until the selection of fifty numbers. Then again, using the Counterfeit Table, people will be divided into two groups of intervention and control. 25 pairs will be assigned to the intervention group and 25 individuals will be assigned to 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

Shiraz University of Medical Sciences and Health Services

Street address

Building of Shiraz University of Medical Sciences,

Emam Hossein Square, Zand Street

City
Shiraz

Province
Fars

Postal code
713451978

Approval date
2017-05-20, 1396/02/30

Ethics committee reference number
IR.SUMS.REC.1396.29

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

Social and psychological adjustment

Timepoint

Before the intervention, after the end of the intervention

Method of measurement

Bell Social Psychosocial Compliance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Interventions include eight cognitive-behavioral training sessions. Each training session will be held for a period of 90 minutes. 30 minutes delivering lectures, 30 minutes of assignments, 30 minutes of group discussion

Category

Lifestyle

2

Description

Intervention in the control group (the control group will not receive any cognitive-behavioral psychotherapy interventions during the interventions, only general treatment will be performed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne-Sina Psychiatric Hospital

Full name of responsible person

Zakiye Ghelbash

Street address

Hafez Avenue., Ebne-Sina Hospital

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz, Central Building Of Shiraz University Of Medical Sciences, Zand St.

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Web page address

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

Zakiye Ghelbash

Position

Student

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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Ladan Zarshenas

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Person responsible for updating data

Contact

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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

The data from the study after the analysis will be reported in full

When the data will become available and for how long

Starting data access is six months after the results are printed

To whom data/document is available

Researchers working in scientific and research institutes

Under which criteria data/document could be used

Copying and printing data is illegal

From where data/document is obtainable

Fatemeh School of Nursing & Midwifery Shiraz

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

Send an email to the research designer who agrees if the requirements are met

Comments