

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effects of cognitive behavior group therapy on suicidal ideation and self-esteem in patients with major depression

Protocol summary

Summary

This is a clinical trial study to elucidate the effect of the behavioral cognitive group therapy on the suicidal ideation and self-esteem in patients that suffer from major depression. The study is established in Rajaei hospital in Yasouj city. Among all the hospitalized patients, 40 patients participate in this project and all are selected randomly. The volunteers are arranged in control and experimental groups. In brief, inclusion criteria is depression score higher than 29 according to "Beck depression questionnaire" and exclusion criteria are no tendency in patient to participate in the study. After getting informed consent, data collection will be established by "Beck depression questionnaire". Moreover, the intervention in experimental group includes cognitive behavioral group therapy in 8 sessions. Both groups continue their drug therapy in all steps of study. The variables are: suicidal ideation and self-esteem.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013026263N1**

Registration date: **2016-11-30, 1395/09/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-30, 1395/09/10

Registrant information

Name

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Name of organization / entity

Yasouj University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Yasouj University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of cognitive behavior group therapy on suicidal ideation and self-esteem in patients with major depression

Public title

How does suicidal thoughts and self-esteem can be affected by cognitive behavior group therapy in patients who suffer from major depression?

Purpose

Treatment

Inclusion/Exclusion criteria

The following are the criteria for inclusion to the study: 1- Patients who have been diagnosed with major depression by an expert specialist physician (psychiatrist) according to the DSM V criteria for major depression. 2- Patients who have Beck depression score higher than 29. 3- Patients who have Beck suicidal score higher than 4. 4- Before enrolling the patients into the clinical trial all of

them have to consent to participate in this study. So, informed consent is collected according to guidelines from the fields of medical ethics and research ethics. Also, the exclusion factors are listed below: 1- Patients who have been diagnosed with other psychiatric disorders by an expert specialist physician (psychiatrist). 2- Lack of tendency of the patients to continue participation in the study or moving to other clinics.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Due to the sample size, random number table uses. So, patients who have odd numbers classified in the experimental (interventional) and who have even number classified in control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, No. 105, Blvd. Shahid Motahari, Yasouj, Iran

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Postal code

7591741417

Approval date

2014-11-01, 1393/08/10

Ethics committee reference number

93080108

Health conditions studied

1

Description of health condition studied

Major Depression

ICD-10 code

F92.0

ICD-10 code description

Depressive conduct disorder

Primary outcomes

1

Description

Suicide ideation

Timepoint

Pre-intervention , One week after intervention , One month after intervention

Method of measurement

Beck suicide ideation questionnaire

Secondary outcomes

1

Description

Self-esteem

Timepoint

Pre-intervention , One week after intervention , One month after intervention

Method of measurement

Rozenberg self-esteem questionnaire

Intervention groups

1

Description

In experimental group beside the routine drug therapy that was prescribed by the relevant psychiatrist, the group therapy with a behavioral cognitive approach will establish by clinician or a clinical technician (a clinical psychologist or an expert nurse). In addition, this intervention includes 2 session per week for 4 continuous weeks. It should be noted that each session group therapy will be 90 minutes.

Category

Behavior

2

Description

The control group will continue to take their routine drugs that was prescribed by the relevant psychiatrist. So, unlike the experimental group there is no intervention for this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajai hospitals and health clinic of Shahid Mofateh

Full name of responsible person

Mehran Pouzesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Yasouj University of Medical Sciences

Full name of responsible person

Mehdi Akbar Tabar

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Yasouj University of Medical Sciences, No. 2, Shahid Jalil street, Yasouj, Iran

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Yasouj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Yasouj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ardeshir Afrasyabifar

Position

Associate professor of nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty