

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 are 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 arrange 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 establish 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

Amin Haghgoo

###### Name of organization / entity

Yasouj University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 74 1333 7251

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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 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

##### **City**

Yasuj

##### **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

**Street address**

No. 40, Imam Hossein Sq, Shahid Rajai psychiatric hospital , Yasouj, Iran

**City**

Yasouj

## 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

**Street address**

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

**City**

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

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**Full name of responsible person**

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## Person responsible for scientific inquiries

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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*