

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Efficacy of cognitive behavioral group therapy and family psycho-education and pharmacotherapy in improving symptoms of major depressive disorder women patients

Protocol summary

Summary

The aim of the present study is to determine the impact of cognitive behavioral group therapy and family psycho-education alongside pharmacotherapy on symptoms of depressed patients. This is a clinical trial using convenience sampling method to randomly recruit 60 patients admitted with major depression from psychiatry patients in Hajar Hospital Shahrekord . The patients were randomly allocated into three groups, each consisting of 20 patients. The first group underwent pharmacotherapy as well as cognitive behavioral group therapy. The second group received pharmacotherapy, cognitive behavioral group therapy and family psycho-education. The third group, which served as the control group, only received pharmacotherapy. Beck Depression Inventory II was applied to all three groups before and after therapeutic intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111298253N1**

Registration date: **2012-01-24, 1390/11/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-24, 1390/11/04

Registrant information

Name

Sayed Kamal Solati

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38133338157

Email address

kamal_solati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2010-11-11, 1389/08/20

Expected recruitment end date

2011-02-18, 1389/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of cognitive behavioral group therapy and family psycho-education and pharmacotherapy in improving symptoms of major depressive disorder women patients

Public title

Effect of psychological intervention on symptoms and preventing recurrence depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: - At least five criteria from the nine diagnostic criteria have been present during the two week period with DSM-IV - The presence of criteria above two weeks at least. - Female sex The minimum level of literacy in primary. - Participate of volunteered in the project. Exclusion criteria: - The presence of periods of manic and hypomanic states. - The presence of organic

damage and cognitive dysfunctions such as dementia and mental retardation. - The presence of periods of delusion and hallucinations symptoms. -A history of receiving ECT.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahrekord University of Medical Sciences

Street address

University of Medical Sciences, Kashani street,
Shahrekord

City

Shahrekord

Postal code

8815713471

Approval date

2011-08-02, 1390/05/11

Ethics committee reference number

89-9-9

Health conditions studied**1****Description of health condition studied**

Major depression disorder

ICD-10 code

F33

ICD-10 code description

Recurrent Depressive Disorder

Primary outcomes**1****Description**

Dypression symptoms

Timepoint

Before of intervention,After intervention,Follow-up

Method of measurement

Beck Depression Inventory -2

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Cognitive - Behavior group therapy
with drug therapy

Category

Behavior

2**Description**

Control group: drug therapy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychiatry Ward ,Hajar Hospital .Parastar
St.Shahrekord ,Iran

Full name of responsible person

Dr.Sayed Kamal Solati

Street address

Psychiatry Ward ,Hajar Hospital .Parastar
St.Shahrekord ,Iran

City

Shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

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City

Shahrekord

Grant name

89-9-9

Grant code / Reference number

89-9-9

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

Yes

Title of funding source

Shahrekord 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**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Sayed kamal Solati

Position

PhD in Psychology - Assistant professor

Other areas of specialty/work**Street address**Psychiatry Ward,Hajar Hospital,Paraster St.
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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