

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The efficacy of combination of behavioural activation and drug treatment therapies in depressed inpatients

Protocol summary

Summary

This is a randomized controlled trial. The aim of the trial was to assess the efficacy of combination of behavioural activation and drug treatment therapies in depressed inpatients. For this purpose we compared three intervention groups including: Behavioral activation group receiving behavioral activation + drug treatment; Movie group participating in sessions to watch movies instead of behavioural activation to neutralize the therapist's effect + drug treatment; and Control group with no behavioral intervention receiving only drug treatment. 24 depressed inpatients were recruited. Inclusion criteria: Minimum guidance school education (total educational years of at least 8 years), age between 20 and 50, diagnosis of depression. Exclusion criteria: Having the features of psychosis, be a candidate for electroconvulsive therapy, having suicidal thoughts. Level of depression was assessed before and after intervention in each patient. The measurements were repeated 2 month after intervention as well. The Beck Depression inventory was used to measure depression. The results were compared in the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009184770N1**
Registration date: **2010-11-08, 1389/08/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-08, 1389/08/17

Registrant information

Name

Samad Fereidooni

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 0218

Email address

fearidonys@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of combination of behavioural activation and drug treatment therapies in depressed inpatients

Public title

The efficacy of combination of behavioural activation and drug treatment therapies in depressed inpatients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Minimum guidance school education (total educational years of at least 8 years), age between 20 and 50, diagnosis of depression. Exclusion criteria: Having the features of psychosis, be a candidate for electroconvulsive therapy, having suicidal thoughts.

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

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

IUMS- Tehran Psychiatric Institute

Street address

Tehran Psychiatric Institute

City

Tehran

Postal code

1443813444

Approval date

2010-03-10, 1388/12/19

Ethics committee reference number

312Ī

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Depression

Timepoint

pre test, post test, 2 month follow up

Method of measurement

Beck Depression Inventory-II

Secondary outcomes

empty

Intervention groups

1

Description

Behavioral intervention group: N=8, they received 7 sessions of behavioral activation each lasting 90 minutes over a 4 weeks period and their standard drug treatment

Category

Behavior

2

Description

Movie watching group: N=8, they received 7 sessions of watching movies the same as the behavioral intervention group to neutralize the therapist's effect over a 4 weeks period plus their standard drug treatment

Category

Behavior

3

Description

Control group with no behavioral intervention: N=8 the received only the standard drug treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Psychiatric Hospital

Full name of responsible person

Samad Fereidooni (post graduate student)

Street address

Shiraz Psychiatric Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of medical science

Full name of responsible person

Dr Abbas Motavallian, Vice Chancellor for research

Street address

Iran University of medical science - Tehran Psychiatric Institute

City

Tehran

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, Iran University of medical science

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

Shiraz Psychiatric Hospital

Full name of responsible person

Samad Fereidooni

Position

post graduate student

Other areas of specialty/work

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Samad Fereidooni and Banafsheh Gharaei

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SAMAD FEREIDOONI

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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