

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

A Randomized Controlled Trial of Behavioral Activation and Treatment As Usual in the Acute Treatments of Adults with Major Depressive Disorder.

Protocol summary

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Summary

Our purpose in this study is comparing two treatment approaches, behavioral activation and treatment as usual. 80 patients, age 18 to 70 year old in Kurdistan province is randomly selected into two equal groups. The first group will receive Sertraline 25 mg daily for the first week, 50 mg for the second and third weeks, 75 mg for the fourth and fifth weeks and 100 mg for the sixth week and until the end of the treatment. The second group will receive 16 session behavioral activation for the three months. The success of the depression treatment and the rate of relapse after one year of treatment will be compared to each other.

Recruitment status

Recruitment complete

Funding source

Medical University of Kurdistan and Maastricht University.

Expected recruitment start date

2009-10-22, 1388/07/30

Expected recruitment end date

2010-09-14, 1389/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807192573N1**

Registration date: **2010-01-16, 1388/10/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-16, 1388/10/26

Registrant information

Name

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Name of organization / entity

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Email address

Scientific title

A Randomized Controlled Trial of Behavioral Activation and Treatment As Usual in the Acute Treatments of Adults with Major Depressive Disorder.

Public title

A Randomized Controlled Trial of Behavioral Activation and Treatment As Usual in the Acute Treatments of Adults with Major Depressive Disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : diagnosis of major depression according to the SCID-I, severity above 19 on the BDI and 13 on the HRSD, age 18-70, written consent to participate with the study. Exclusion criteria : if they have a life time diagnosis of bipolar disorder, organic brain syndrome, psychosis or mental retardation. Additional exclusion criteria are: substantial and imminent suicide risk; a current (e.g., within the past six months) or primary diagnosis of alcohol or drug abuse or dependence or a positive toxicology screen; a primary diagnosis of panic disorder, obsessive-compulsive

disorder, psychogenic pain disorder, anorexia, or bulimia. In addition, participants who did not respond favorably within the preceding year to medication will be excluded. Participants who have unstable medical condition and using any medication that would complicate the administration of antidepressant medication (medication in my study), or have a known allergy to medication in this study will be excluded. Moreover, women who are pregnant or maybe want to be pregnant will be excluded. Lastly, participants have to be able to read and understand the questionnaires and interviews used in the study.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Medical Ethics, Second Session

Street address

Medical University of Kurdistan, Ghods Hospital, Ghods Avenue, Pasdaran Street, Sanandaj, Kurdistan. Iran

City

Sanandaj

Postal code

Approval date

empty

Ethics committee reference number

8017 پ 14 پ

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Treatment of major depressive disorder

Timepoint

Before intervention, in the middle of Intervention (45 days after starting treatment) and after treatment (after 3 months treatment duration).).

Method of measurement

In BA, by BDI-II and In TAU, HRSD is used.

Secondary outcomes

1

Description

Prevention and relapse of major depressive disorder

Timepoint

One year after termination of the treatment

Method of measurement

In BA, by BDI-II and In TAU, HRSD is used.

Intervention groups

1

Description

In behavioral activation group, 16 sessions of BA treatment, for the first month every week two sessions 50 minutes and for the second and third months of the treatment, every week one session will be held.

Category

Behavior

2

Description

Sertraline 25 mg daily for the first week, 50 mg for the second and third weeks, 75 mg for the fourth and fifth weeks and 100 mg for the sixth week and until the end of the treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods Hospital

Full name of responsible person

Latif Moradveisi

Street address

Sanandaj

City

Sanandaj

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

Medical university of Kurdistan and Maastricht University

Full name of responsible person

Mohamadzadeh and Gharibi- Reserach center

Street address

Sanandaj- Medical University of Kurdistan

City

sanandaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Medical university of Kurdistan and Maastricht University

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**

Maastricht University

Full name of responsible person

Latif Moradveisi

Position

PhD student.

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Web page address**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*

