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

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.

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

Latif Moradveisi

Name of organization / entity

Maastricht University, the Netherlands-Medical University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 87 1728 7047

Email address

latif.moradveisi@maastrichtuniversity.nl

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

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 preceeding 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 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 treament (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.
Other areas of specialty/work
Street address
Sanandaj
City
Sanandaj
Postal code
Phone
+98 918 784 8047
Fax
Email
latif.moradveisi@maastrichtuniversity.nl
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Medical University of Kurdistan And Maastricht University
Full name of responsible person
Latif Moradveisi
Position
PhD Student
Other areas of specialty/work
Street address
Sanandaj, Medical University of Kurdistan
City
Sanandaj
Postal code
Phone
+98 87 1728 7047
Fax
Email
lmoradveisi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Maastricht University and Medical University of Kurdistan
Full name of responsible person
Latif Moradveisi
Position
PhD student
Other areas of specialty/work
Street address
Sanandaj, Medical University of Kurdistan
City
Sanandaj
Postal code
Phone
+98 87 1728 7047
Fax
lmoradveisi@gmail.com
Email
lmoradveisi@gmail.com
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

Data Dictionary	*empty*