

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of efficacy of emotion regulation in patient with major depressive disorder on ssri treatment

Protocol summary

Summary

This study is a pre and post-examination using random sampling method. The statistical population is all the outpatients in Akhavan clinic and private practicing professors' offices that are diagnosed with major depression disorder based on DMS-IV-TR criteria. The random sampling was done so that 12 people were selected from all the qualified volunteers for the study. The patients are on SSRI pharmaceutical treatment(Tab sertraline 100mg) as well as psychotherapeutic treatment. Another 12 people group on SSRI treatment(Tab sertraline 100mg) are selected as the control group. The severity of depression symptoms is measured in session 1; session 6; session 12 with Beck depression inventory(BDI). The efficacy of emotion regulation psychotherapy in major depression symptoms is compared in two groups at the end of research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102624711N1**

Registration date: **2016-01-17, 1394/10/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Azad

Name of organization / entity

University of Social Welfare and Rehabilitation
Sciences

Country

Iran (Islamic Republic of)

Phone

Email address

azad@irimc.org

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2015-11-16, 1394/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of emotion regulation in patient with major depressive disorder on ssri treatment

Public title

Efficacy of emotion regulation in major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 25 to 45; minimum high school diploma education; Dominate in persian language psychologically minded; diagnosed with major depression disorder based on DSM-IV TR criteria; voluntarily agreement on the study participation Exclusion criteria: symptoms of neuroticism and mania; drug abuse history; noticeable suicidal thoughts; simultaneous symptoms of borderline personality disorder and anti-social disorder; reluctance on continuing the treatment; receiving other psychotherapeutic treatments as well as current treatment; need for hospitalization or ECT while under

treatment

Age
From **25 years** old to **45 years** old

Gender
Both

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

University of Social Welfare and Rehabilitation
Sciences

Street address

Kodakyar Ave, daneshjo Blvd, Evin

City

Tehran

Postal code

1985713834

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

IR.USWR.REC.1394.29

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

sadness

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

2

Description

paranoia

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

3

Description

last breakage

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

4

Description

anhedonia

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

5

Description

guilt feeling

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

6

Description

sense of punishment

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

7

Description

self dislike

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

8

Description

self criticism

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

9

Description

suicidal idea or tendency

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

10

Description

crying

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

11

Description

unrest

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

12

Description

loss of interest

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

13

Description

undecision

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

14

Description

worthless

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

15

Description

lack of energy

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

16

Description

sleep disturbance

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

17

Description

irritability

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

18

Description

appetite disturbance

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

19

Description

concentration disturbance

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

20

Description

fatigue

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

21

Description

hyposexuality

Timepoint

session1,session 6,session12

Method of measurement

beck depression inventory

Secondary outcomes

1

Description

emotion regulation

Timepoint

session1,session 12

Method of measurement

emotion regulation questionnaire

Intervention groups

1

Description

We use medical therapy(tab sertraline 100mg/daily)and 12 session emotion regulation psychotherapy in intervention group

Category

Treatment - Other

2

Description

We use only medical therapy(tab sertraline 100mg/daily) in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatry hospital

Full name of responsible person

Dr.Ali nazeri

Street address

Razi hospital, shahid rastegar blvd, shahrerey

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr.Hamidreza Khanke

Street address

Kodakyar Ave, Daneshjo street, Evin

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Azad matari

Position

Resident of psychiatry

Other areas of specialty/work

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Person responsible for updating data

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[http://razi.uswr.ac.ir/index.aspx?fkeyid=&siteid=9&pa
geid=830](http://razi.uswr.ac.ir/index.aspx?fkeyid=&siteid=9&pageid=830)

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