Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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. Another12 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 efficasy 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 psychologicall 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 sertralin 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
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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
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Azad matari
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Person responsible for updating data

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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