Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of adjunctive exercise in patients with major depressive disorder(MDD) receiving routine pharmacotherapy

Protocol summary

Summary

Objective: We studied the effect of adding exercise and regular physical activity on usual treatments of MDD . Method: 46 depressed patients according to DSM-5 criteria from Roozbeh hospital ward and outpatient clinics were selected to conduct Interventional clinical trial based on inclusion and exclusion criteria and after obtaining written consents, were divided randomly into two equal groups. At the beginning of the plan, two people from the control group and two people from the sample group were excluded due to non-compliance with the terms of the plan and then a group of sample including 21 people received only the usual drug treatment and a group of control including 21 people received the drug treatment plus exercise (according to protocol) both for 8 weeks. The general conditions for acceptance of patients with MDD were between the ages of 18 to 64 years. Exclusion criterias were major acute, chronic medical illness and acute , chronic psychiatric illness except MDD ,and acute suicidal ideations and substance abuse disorders . Patients before the intervention and at the end, were checked with the physical and medical profiles and quality of life and general health by questionnaire. At the beginning and end of the study, patients evaluated by depression and anxiety beck & Hamilton tests and PITT test was carried out for sleep quality and Results were analyzed by SPSS 20 instruments that, the quality and Results were analyzed that, the main Consequence was depression and Secondary Consequences were anxiety, sleep, medical profile and body mass index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111630924N1**
Registration date: **2017-01-19, 1395/10/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-01-19, 1395/10/30

Registrant information

Name
Ŝeyyed Azim Seyd

Name of organization / entity
Tehran University of Medical Sciences (TUMS)

Country
Iran (Islamic Republic of)

Phone
+98 21 6663 3114

Email address
mokriazr@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of adjunctive exercise in patients with major depressive disorder(MDD) receiving routine pharmacotherapy

Public title

Effects of exercise in the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion: Major acute and cronic Medical illness psychiatric disorders except Major Depressive Disorder ,and acute suicidal ideations and substance abuse disorders. Inclusion: Patients with Major Depressive Disorder; Age between 18 to 64 Years

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Method of randomizing: Table of random numbers

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Tehran university of medical sciences , enghelab street

City

Tehran

Postal code

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.Tums.REC.1394.1194

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32 : F32

ICD-10 code description

Depressive episode ; Mild depressive episode with and without somatic symptoms,Moderate depressive episode with and without somatic symptoms,Sever depressive episode without psychotic symptoms,Recurrent depressive disorder current episode mild,Recurrent d

Primary outcomes

1

Description

Major depressive disorder

Timepoint

Beginning and end of Exercise plan (Baseline and 8 weeks later)

Method of measurement

Interview, questionaire, laboratory tests

Secondary outcomes

1

Description

Sleep

Timepoint

Onset and end of exercise plan

Method of measurement

Sleep questionnaire of pitseburg

2

Description

Anxiety

Timepoint

Onset and final of exercise plan

Method of measurement

Interview, anxiety Questionnaires of beck and hamilton

3

Description

General health and qualithy of life

Timepoint

Onset and end of exercise plan

Method of measurement

General Heaith and Qualithy of life questionnaire

4

Description

medical profile

Timepoint

Onset and end of exercise plan

Method of measurement
laboratory tests

5

Description
Body mass index
Timepoint
Onset and end of exercise plan
Method of measurement
Scale to weith

Intervention groups

1

Description
Control group: In this group only treated with pharmacotherapy equal interventional pharmacotherapy namely specific serotonin reuptake inhibitor antidepressants treated.
Category
Behavior

2

Description
Interventional group : Randomized Clinical trail 8 weeks adjunctive exercisetherapy with kind of airobic plus light strength three times a week per part 45 minutes aded to routin pharmacotherapy treatment evaluated for MDD in intervention group.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Dr Seyyed Azim Seyd
Street address
Roozbeh hospital , South karegar street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tehran University of Medical Science
Full name of responsible person
Mrs Ahmadi
Street address
Vice chancellor for research of Tehran University of Medical science , Intersection ghods St. , Enghelab St.
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 of Tehran 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
Roozbeh hospital research center
Full name of responsible person
Dr seyed azim seyd
Position
Psychiatrist
Other areas of specialty/work
Street address
Roozbeh Hospital , south karegar St.
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Roozbeh Hospital research center
Full name of responsible person
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Position
Psychiatrist
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Street address
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Person responsible for updating data

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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
Data Dictionary
empty