

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Can exercise enhance the positive effects of sertraline in patients with major depressive disorders? A randomized clinical trial

Protocol summary

Study aim

The aim of study was to investigate the effect of exercise on depression and anxiety scores and sleep quality of middle aged patients with major depressive disorders.

Design

This study is designed as a randomized clinical trial with blinded outcome assessor with two parallel arms having an allocation ratio of 1:1. The minimum number of patients required for the study in each group was 15. Participants were randomly assigned to either control or study group with a 1:1 allocation ratio by TENALEA, which is an online, central randomization service using permuted blocks of random sizes.

Settings and conduct

Patients were assigned to the study voluntarily and were informed about the study using notifications in outpatient clinics and a briefing by the researchers in "Roozbeh Hospital clinic". Since exercise is an overt behavior, there was not the possibility of blinding the participants and care providers. Thus, only those assessing outcomes were blinded.

Participants/Inclusion and exclusion criteria

The candidates were diagnosed with major depression on sertraline. Exclusion criteria were defined as: psychosis; suicidal actions or thoughts; self-mutilation; chronic diseases associated with vital organs such as heart, lungs, and kidneys; and bone and soft tissue disorders which made it impossible to comply with the exercise schedule.

Intervention groups

The study group received sertraline plus regular supervised exercise, 60 minutes a session, three times a week for a total duration of 8 weeks. The control group received only sertraline for 8 weeks.

Main outcome variables

Depression score in Beck depression inventory;
Depression score in Hamilton depression scale; Anxiety score in Hamilton anxiety scale; Anxiety score in Beck anxiety inventory; Sleep quality index in Pittsburg sleep

quality index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180506039542N1**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **retrospective**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

Registration date

2018-06-29, 1397/04/08

Registrant information

Name

Bitra Tavana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 0227

Email address

b-tavana@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2016-02-04, 1394/11/15

Actual recruitment start date

2015-05-14, 1394/02/24

Actual recruitment end date

2016-04-18, 1395/01/30

Trial completion date

empty

Scientific title

Can exercise enhance the positive effects of sertraline in patients with major depressive disorders? A randomized clinical trial

Public title

Effects of exercise in major depression disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients were diagnosed with major depression based on DSM-V criteria All the patients were on sertraline prior to study Patients were healthy and were able to execute regular exercise

Exclusion criteria:

Patients who had psychosis Patients who had suicidal actions or thoughts Patients who had self-mutilation Patients who had chronic diseases associated with vital organs such as heart, lungs, and kidneys Patients who had bone and soft tissue disorders which made it impossible to comply with the exercise schedule

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned to either control or study group with a 1:1 allocation ratio by TENALEA, which is an online, central randomization service using permuted blocks of random sizes. In order to confirm allocation concealment, the randomization code was not released by the service until the patient had been enrolled in the study, which happened after all baseline measurements have been completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since exercise is an overt behavior, there was not the possibility of blinding the participants and care providers. Thus, only those assessing outcomes were blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, 6th floor, Central Building of Tehran University of Medical Sciences, Corner of Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2015-05-03, 1394/02/13

Ethics committee reference number

IR.TUMS.REC.1394.1194

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

V

ICD-10 code description

Mental and behavioral disorders

Primary outcomes

1

Description

Depression score in Hamilton depression scale

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

Hamilton depression scale

2

Description

Depression scores in Beck depression inventory

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

Beck depression inventory

3

Description

Anxiety scores in Hamilton anxiety scale

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

Hamilton anxiety scale

4

Description

Anxiety scores in Beck anxiety inventory

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

Beck anxiety inventory

5

Description

Sleep quality index in Pittsburg sleep quality index

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

Pittsburg sleep quality index

Secondary outcomes

1

Description

Body mass index

Timepoint

At the beginning of the study (prior to initiation of the intervention) and eight weeks after starting of the exercise

Method of measurement

The body weight (kilograms) divided by the square of the body height (square meters)

Intervention groups

1

Description

Control group: The control group were patients diagnosed with major depression on sertraline prior to this study with a dosage range of 50 to 150 mg daily. They continued to receive sertraline for 8 weeks (during the study).

Category

Treatment - Drugs

2

Description

Intervention group: Patients assigned to the test group were asked to perform regular exercises, 60 minutes a session, three times a week, under the supervision of a

registered trainer for a total duration of 8 weeks. Physical activity was scheduled as aerobic, stretching and strengthening exercises. Patients were asked to do 15 minutes of warm up, and 40 minutes of stretching and strengthening exercises followed by 5 minutes of cooling down with low intensity activities. Patients enrolled in the test group received sertraline prior to this study with a dosage range of 50 to 150 mg daily which continued during the study.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr Azarakhsh Mokri

Street address

No. 606, South Karegar St., District 11, Roozbeh Hospital

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 9151

Fax

+98 21 5541 2756

Email

b-tavana@farabi.tums.ac.ir

Web page address

<http://roozbehhospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

Vice Chancellor for Research and Technology, 6th floor, Central Building of Tehran University of Medical Sciences, Corner of Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417863181

Phone

+98 21 6670 6141

Fax

+98 21 6670 6141

Email
msahrai@sina.tums.ac.ir
Web page address
<http://vcr.tums.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Bitva Tavana
Position
General physician, researcher
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
No.7, Jalal-e-Al-e-Ahmad Highway. Sports and Exercise Research Center, the Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
14395-578
Phone
+98 21 8863 0227
Fax
+98 21 8800 3539
Email
b-tavana@farabi.tums.ac.ir
Web page address
<http://ni.tums.ac.ir/smr/fa/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Bitva Tavana
Position
General physician, researcher
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
No.7, Jalal-e-Al-e-Ahmad Highway. Sports and Exercise Research Center, the Tehran University of Medical Sciences
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+98 21 8800 3539
Email
b-tavana@farabi.tums.ac.ir
Web page address
<http://ni.tums.ac.ir/smr/fa/>

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Bitva Tavana
Position
General physician, researcher
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
No.7, Jalal-e-Al-e-Ahmad Highway. Sports and Exercise Research Center, the Tehran University of Medical Sciences
City
Tehran
Province
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Postal code
14395-578
Phone
+98 21 8863 0227
Fax
+98 21 8800 3539
Email
b-tavana@farabi.tums.ac.ir
Web page address
<http://ni.tums.ac.ir/smr/fa/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available