

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of 8 weeks of physical activity and mindfulness-based stress reduction program on psychological factors, sleep quality and pattern in patients with major depression (clinical trial study with a control group)

Protocol summary

Study aim

Comparison of the effect of 8 weeks of physical activity and mindfulness-based stress reduction program on psychological factors, sleep quality and pattern in patients with major depression (clinical trial study with control group)

Design

Clinical trials with control group, parallel groups, single-blind, randomized, phase 3, 60 patients

Settings and conduct

This study is a single-blind trial. The study sample population consists of all Patients with Methamphetamine-Induced Mood Disorder referring to Farabi Hospital in Kermanshah, that 60 persons will be selected in the available method and randomly will be divided into two groups. The first group will receive a physical activity program, the second group will receive a mindfulness-based stress reduction treatment program (MBSR), the third group will receive a combination of physical activity. All subjects in all four groups will assess by completing a questionnaire at the baseline, 8 weeks later and four weeks after the end of the study in the follow-up test.

Participants/Inclusion and exclusion criteria

Both genders; Major Depression Disorder diagnosed by a psychiatrist, Major Depression Disorder diagnosed according to Diagnostic and Statistical Manual of Mental Disorders fifth edition and Beck questionnaire; having major depressive symptoms for at least 2 weeks, not having chronic physical illnesses. Patients who are not agree to participate in the study will be excluded.

Intervention groups

The physical activity will include aerobic exercise for 8 weeks and 2 sessions. The MBSR group includes breathing exercises, mindfulness, and commitment and acceptance. The combination group includes MBSR and

aerobic exercise. Sertraline 50 to 200 mg daily for the control group.

Main outcome variables

Depression symptoms, anxiety, stress, emotion regulation, insomnia severity, sleep quality,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210119050079N1**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Ebrahim Norouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3725 3847

Email address

ebrahim.norouzi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-11-25, 1400/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 8 weeks of physical activity and mindfulness-based stress reduction program on psychological factors, sleep quality and pattern in patients with major depression (clinical trial study with a control group)

Public title

Comparison of the effect of 8 weeks of physical activity and mindfulness-based stress reduction program on psychological factors, sleep quality and pattern in patients with major depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Major depression disorder diagnosed by a psychiatrist
Diagnosis of major depression disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition: DSM-5 and Beck questionnaire Have major depressive symptoms for at least 2 weeks

Exclusion criteria:

Patients who are not agree to participate in the study will be excluded

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into four equal groups (1. physical activity, 2. mindfulness, 3. combination of physical activity and mindfulness and 4. control) based on a randomized ten-block design using random allocation software. To randomly assign 60 patients to the four groups, six different blocks of 10 different letters A and B and C and D, which indicate physical activity, mindfulness, combination of physical activity and mindfulness and control groups respectively, will be initially created. These blocks then will be numbered from one to ten. In the next step, each of these blocks will be randomly selected by performing lottery using 10 card with letters from 1 to 10 on them. Thus, in each lottery, by selecting a block, a combination of 6 letters of the letters A and B and C and D will be obtained. At the

end of the 10 drawings, after selecting 10 blocks, a total of 60 letters A and B and C and D will be obtained. The resulting combination of letters A and B and C and D is single, and will be placed in 60 separate and sealed envelopes, respectively. following each patient recourse, an envelope will be opened to determine the group of that patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome examiners (people who distribute questionnaires among patients) are blind to the type of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.KUMS.REC.1400.153

Health conditions studied**1****Description of health condition studied**

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes**1****Description**

Symptoms of depression
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Beck Questionnaire

2

Description
Symptoms of anxiety
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Beck Questionnaire

3

Description
Perceived stress
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Cohen Questionnaire

4

Description
Emotion regulation
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Emotion Regulation Problems Questionnaire

5

Description
sleep quality
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Pittsburgh Questionnaire

6

Description
sleep pattern
Timepoint
before intervention- 8 weeks later- 4 weeks later
Method of measurement
Insomnia Severity Scale and sleep tables

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group will receive aerobic exercise in two months. The exercises will include two parts: static aerobic exercise and dynamic aerobic

exercise. In general, the exercises will consist of 4 main parts. 1) warm up; It will include stretching movements, hypothetical line movements, cross-arm movements, arm rotations, neck rotations, cross-leg movements, sit-ups, 2) static aerobic exercise; Includes climbers walking, Palank, Palank with knee touch, and ski movement. 3) Dynamic aerobic exercise; It will include jogging at 70% of your maximum heart rate. 4) cooling down; It will include stretching, cross-linking, sitting, lying down and cradle movement. Exercises are performed with behavioral techniques and with the guidance of sports instructors and in a modified manner in accordance with the physical fitness of patients. The intervention will be done in 8 weeks and 2 sessions per week. Patients engage in aerobic exercise for 30 to 45 minutes per session.

Category
Behavior

2

Description
Intervention group: The group will receive mindfulness based stress reduction program in two months. Mindfulness based stress reduction will be done at 8 weeks and twice a week. The first week includes training and will discuss the MBSR and its potential for mental health. The second week is the stage of communication and conceptualization of mindfulness. The third week will include mindfulness training and dealing with obstacles. The fourth week of identifying values is the distinction between value and purpose. The fifth week will be the practice of mindfulness and staying in the present. The sixth week will be devoted to cognitive, emotional and behavioral flexibility. The seventh week will be about creating a sense of acceptance and compassion in patients. Finally, in the eighth week, the composition and coherence of the components of mindfulness will be considered.

Category
Behavior

3

Description
Intervention group: The group will receive combination of physical activity and mindfulness intervention in two months. Training on non-judgment and acceptance will be considered. Patients will learn to look at their goals and values without negative or positive judgments. Moreover, the physical activity will be considered as a training in the mindfulness intervention. In this way, the importance of physical activity as a factor in overcoming negative thoughts and reaching the present will be discussed. Patients will spend half of the treatment session on physical activity and the other half on the MBSR program. The intervention will be done in 8 weeks and 2 sessions per week.

Category
Behavior

4

Description

Control group: The group will receive Sertraline (Tolid Daro company) treatment in two months. Sertraline is prescribed at a dose of 50 to 200 mg per day as medication (control group). In addition, Patients are monitored by telephone twice a week in the control group. They are questioned about their physical and psychological condition.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Habibolah Khazaie

Street address

Isar square, Farabi Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3827 6683

Email

hakhazaie@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3836 0014

Email

rkhodarahmi@mbrc.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Habibolah Khazaie

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Sleep Disorders Research Center, Farabi Hospital, Doulatabad Blvd., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6719851151

Phone

+98 83 1824 9353

Email

hakhazaie@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Habibolah Khazaie

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Farabi Hospital, Sleep Disorders Research Center, Department of Psychiatry, Kermanshah University of Medical Sciences, Dolatabad Blvd, PO box: 6719851151, Kermanshah, Iran

City

Kermanshah
Province
Kermanshah
Postal code
: 6719851151
Phone
+98 83 1824 9353
Email
hakhazaie@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ebrahim Norouzi
Position
PostDoc
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Farabi Hospital, Sleep Disorders Research Center,
Department of Psychiatry, Kermanshah University of
Medical Sciences, Dolatabad Blvd, PO box:
6719851151, Kermanshah, Iran
City
Kermanshah
Province

Kermanshah
Postal code
6719851151
Phone
+98 935 773 5774
Email
ebrahim.norouzi68@gmail.com

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