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 is 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

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Iran (Islamic Republic of)

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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 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 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 an 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 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

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Sponsors / Funding sources

1

Sponsor

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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

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Other areas of specialty/work

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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