Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness referred to exercise therapy unit in outpatient setting

Protocol summary

Study aim

The effect of exercise therapy and lifestyle modification training on the components of metabolic syndrome in patients with severe mental illness

Design

Pretest-posttest

Settings and conduct

The patient's overall performance is determined by the Global Assessment of Functioning (GAF). The patient is checked for metabolic syndrome and the patient's height, weight, blood pressure and waist circumference are measured and BMI is determined and recorded and the patient's level of physical activity is determined based on the interview and 6 min walk test is performed. Some lab tests including fasting blood sugar and lipid profile are requested. 1) 20 sessions of exercise therapy 2) 4 group training sessions of lifestyle modification The lifestyle modification sessions are held by a trained nurse every week in a group manner. The duration of each session is about 45-30 minutes. Patients attend exercise therapy sessions under the supervision of a trainer twice a week for 10 weeks. At the end of 10 weeks, the patient's overall function is determined again and the fasting blood sugar assessment and lipid profile are repeated. The patient's BMI, blood pressure, and waist circumference are measured and recorded again after 5 weeks and at the end of week 10.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe mental illness, in the age range of 18-50 years, in the remission phase and under the medication treatment Exclusion criteria: Patients with a history of substance abuse in the past month, unstable physical or neurological disorders, patients with diabetes mellitus or heart disease, uncontrolled seizures or musculoskeletal disease

Intervention groups

The intervention includes 20 sessions of exercise therapy and 4 sessions of a nutrition education program.

Main outcome variables

weight BMI Waist circumstances Blood pressure FBS and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051765N1**
Registration date: **2021-09-16, 1400/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-16, 1400/06/25**
Update count: **0**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Zahra Mirsepassi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8838 5809

Email address

mirsepassizahra@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-04, 1400/04/13

Expected recruitment end date

2023-07-04, 1402/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness referred to exercise therapy unit in outpatient setting

Public title

The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe mental illness In the remission phase Under the treatments

Exclusion criteria:

Substance use in the last month Presence of any uncontrolled medical or neurological disease Diabetes mellitus Heart disease Uncontrolled seizure Musculoskeletal disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Tehran University of Medical Sciences, Poorsina Ave, Ghods Ave, Enghelab Ave

City

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Province

Tehran

Postal code

1417613151

Approval date

2021-06-22, 1400/04/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.320

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

2

Description of health condition studied

schizoaffective disorder

ICD-10 code

F25

ICD-10 code description

Schizoaffective disorders

3

Description of health condition studied

bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

4

Description of health condition studied

depressive disorders without psychotic feature

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder without psychotic features

5

Description of health condition studied

depressive disorders with psychotic feature

ICD-10 code

F32.3

ICD-10 code description

Major depressive disorder with psychotic features

Primary outcomes

1

Description
Waist circumstance
Timepoint
Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy
Method of measurement
Centimeter tape measure

2

Description
Weight
Timepoint
Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy
Method of measurement
Scale

3

Description
Blood Glucose
Timepoint
Before starting the intervention and after 20 sessions of exercise therapy
Method of measurement
Lab tests

4

Description
Lipid profile
Timepoint
Before starting the intervention and after 20 sessions of exercise therapy
Method of measurement
Lab tests

5

Description
Systolic blood pressure
Timepoint
Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy
Method of measurement
Sphygmomanometer

6

Description
Diastolic Blood pressure
Timepoint
Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy
Method of measurement
Sphygmomanometer

Secondary outcomes

1

Description
Global assessment of functioning
Timepoint
Before the intervention/at the end of the intervention
Method of measurement
GAF scale

Intervention groups

1

Description
The intervention includes exercise therapy and a nutrition education program. The nutrition educational program includes 4 group educational sessions. The intervention to increase physical activity includes 20 sessions of exercise therapy. Nutrition education program: In the first 4 sessions, patients will participate in a group educational session and then receive exercise therapy intervention. In the following sessions, the individual's nutritional habits will be explored and then exercise therapy will be provided. The training sessions will be held by a trained nurse, occupational therapist or psychologist who has participated in a workshop. These sessions are held every week in a group manner (5-8 people). The duration of each session will be about 30-45 minutes. The first session includes being familiar with the team members and reviewing the basics principles of healthy eating. In the second and third sessions, different food categories, the fiber content of foods, different food calories and the importance of physical activity will be explained. In the fourth session, in addition to review the previous contents, the patients' misconceptions about nutrition, will be discussed. The exercise therapy as an intervention to increase physical activity: The exercise program including 5 to 10 minutes of warm-up (low-intensity exercise with flexibility movements), 15 to 30 minutes of aerobic exercise includes stationary and elliptical cycling, 15 minutes of strength training with the device for upper and lower limbs and 5 minutes of cooling. Exercise intervention will be the same for all patients, and aerobic exercise and moderate-intensity strength exercise will be defined according to the Borg table (between 11 and 14). Exercise therapy sessions will be performed twice a week for 10 weeks (20 sessions of exercise therapy) under the supervision of a trained trainer. The patient's vital signs will be recorded by the nurse, before and after the intervention. The exercise program will be performed under the supervision of a coach for 30-45 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Exercise therapy unit in Roozbeh Hospital

Full name of responsible person
Zahra Mirsepassi
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Roozbeh hospital, South Kargar Ave, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr shahin Akhondzadeh
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Web page address
http://medicine.tums.ac.ir/research
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
50
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
Zahra Mirsepassi
Position
Assistant professor of psychiatry
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepassi

Position

Assistant professor of psychiatry

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

According to ethical concerns the data will not be published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publication as a manuscript

When the data will become available and for how long

Three years later

To whom data/document is available

The researchers

Under which criteria data/document could be used

Planning for health promotion

From where data/document is obtainable

The journal

What processes are involved for a request to access data/document

Requesting via email

Comments