

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of drug therapy in combination with exercise and drug therapy alone in the treatment of patients with insomnia

Protocol summary

Study aim

The effect of exercise on symptoms of Insomnia in patients referred to sleep clinic

Design

A randomized, controlled, placebo-controlled clinical trial

Settings and conduct

The study is performed in the sports medicine department of Rasoul Akram Hospital. Patients are selected by randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People who meet Insomnia diagnostic criteria as specified by a psychiatrist; People with systolic and diastolic blood pressure lower than 180 and 100, respectively; People whose activity is less than 30 minutes a day; People who have completed the study consent form. Non-inclusion criteria: People who have or have a history of cardiovascular disease; People who have uncontrolled diabetes; People who have uncontrolled respiratory disease; Patients who are unable to exercise for any reason; Patients whose symptoms of sleep disturbance strongly suggest other sleep disorders other than insomnia, such as sleep apnea and restless leg syndrome.

Intervention groups

Intervention group :Patients with insomnia , In this group, in addition to the medication prescribed for insomnia prescribed by the relevant psychiatrist, the intervention is performed for 3 months in the form of increased aerobic and resistance exercise. Aerobic exercise will be done in the form of walking three days a week, and dumbbell exercises are for large muscle groups and for three days a week. Control group: Patients with insomnia , In this group, there is no intervention other than taking the prescribed medication for insomnia by the relevant psychiatrist.

Main outcome variables

Insomnia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100623004251N12**

Registration date: **2020-02-12, 1398/11/23**

Registration timing: **retrospective**

Last update: **2020-02-12, 1398/11/23**

Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

Haleh Dadgostar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 4050

Email address

dadgostar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2019-12-20, 1398/09/29

Actual recruitment start date

2019-05-21, 1398/02/31

Actual recruitment end date

2019-11-30, 1398/09/09

Trial completion date

2019-11-30, 1398/09/09

Scientific title

Comparative study of drug therapy in combination with exercise and drug therapy alone in the treatment of patients with insomnia

Public title

The effect of exercise on insomnia in patients referred to sleep clinic

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People who have diagnostic criteria for insomnia based on psychiatric examinations People with systolic and diastolic blood pressure of less than 180 and 100, respectively People with less than 30 minutes of activity per day People who have completed the consent form of the study in the study

Exclusion criteria:

People with cardiovascular disease or history of cardiovascular disease People with uncontrolled diabetes People with uncontrolled respiratory illness Patients who are not able to exercise for any reason Patients whose symptoms of sleep disorder strongly suggest other sleep disturbances other than Insomnia, such as sleep apnea and restlessness syndrome

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization. Four blocks of 4 including 2 participants in the intervention group and 2 participants in the control group were used. The blocks were selected by www.sealedenvelope.com.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Shahrara St, Satarkhan St, Tehran. Tehran Province, Iran

City

Tehran

Province

Tehran

Postal code

1467885361

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9411225006

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

insomnia

ICD-10 code

G47.00

ICD-10 code description

Insomnia, unspecified

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

Insomnia

Timepoint

before intervention and 3 month after intervention

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Interventions are increased for 3 months in the form of aerobic and resistance exercise. Aerobic exercise will be performed in the form of walking, 30 minutes daily, three days a week in the first month, 45 minutes a day in the second month and 1 hour a day in the third month with moderate intensity. Twelve weeks of resistance training is considered. Every 4 weeks have same exercise program chosen from 3 models of A, B and C focusing on the large muscles of the lower and upper limbs and central part of the body that will be performed for 3 consecutive days per week. Before each session, patients warm up for 15 minutes with stretching exercises. Every two weeks the weight of the weight will be increased a half kilo so that the first week of every

two weeks is three sets of 10, and the second week is three sets of 15, and the intensity increases gradually every two weeks. At the end of each session cooling down will be done for 5 to 10 minutes. The intervention group will be provided with a summary of these movements and their order through a booklet. The practitioner instructs patients on all movements during the first visit. Patients will record each movement after doing it in the report table given to them.

Category

Lifestyle

2

Description

Control group: patient with insomnia

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e-Akram hospital

Full name of responsible person

Haleh Dadgostar

Street address

Sports Medicine Department, Building No. 1, Hazrate Rasool Akram Hospital, Niayesh Ave, Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

dadgostar.h@iums.ac.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevalian

Street address

Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 1021

Email

motevalian@iums.ac.ir

Web page address

http://vcr.iums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Haleh Dadgostar

Position

Associate professor , Iran University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Sports Medicine Department, Building No. 1, Hazrate Rasool Akram Hospital, Niayesh Ave, Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

dadgostar.h@iums.ac.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Haleh dadgostar

Position

Associate professor , Iran University of Medical

Sciences

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Sports Medicine Department, Building No. 1, Hazrate
Rasool Akram Hospital, Niayesh Ave, Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

dadgostar.h@iums.ac.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Haheh dadgostar

Position

Associate professor , Iran University of Medical
Sciences

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Sports Medicine Department, Building No. 1, Hazrate
Rasool Akram Hospital, Niayesh Ave, Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

dadgostar.h@iums.ac.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sleep quality data available in the pittsburgh
questionnaire

When the data will become available and for how long

From the time the article was published until five years
later

To whom data/document is available

Researchers working in academic centers who
systematically intend to use these findings in meta-
analysis.

Under which criteria data/document could be used

Due to the presence of the authors of this article in the
academic center, there is a need to obtain written
permission from the university to submit data. Therefore,
after requesting data, this data will be sent within 6
months (after university approval).

From where data/document is obtainable

Rasoul Akram Hospital of Sports Medicine Dr. Hale
Dadgostar, Dr. Afsane Basharkhah

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

Upon requesting documentation, the researcher must
obtain a written permission from the research project
and submit the documentation after obtaining
permission. So the estimated time to send the data is
about 6 months after their request.

Comments